EPA Registration #73139-3

PROCESSING REQUEST

Reg # 73139-3 **Decision #** 5410591

Description: CSF Notification

Material Available Electronically (see PPLS):

☐ Electronic Label/Letter Dated

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated

☐ Notification Dated

☒ New CSF(s) Dated 5/21/2018

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Melanie Bolden

Division: AD

Phone: 703 347 0165 **Date:** 6/4/2018

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 22, 2018

Ana Rodriguez-Koster
Agent for Sabre Oxidation Technologies, Inc.
Sabre Oxidation Technologies, Inc.
1891 New Scotland Road
Slingerlands, NY 12159

Subject: Notification per PRN 98-10 – Addition of alternate suppliers
Product Name: DIKLOR G
EPA Registration Number: 73139-3
Application Date: May 7, 2018
Decision Number: 541059

Dear Ms. Rodriguez-Koster:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/21/2018

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, you may contact Melanie Bolden at (703) 347-0165 or via email at Bolden.Melanie@epa.gov.

Sincerely,

Wanda G Jr, for

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Bolden, Melanie

From: Ana Koster <alkoster@lewisharrison.com>
Sent: Tuesday, May 22, 2018 11:57 AM
To: Bolden, Melanie
Cc: OPP AD Ombudsman; Fuller, Demson
Subject: RE: Completed Action: EPA Reg. No. 73139-3

Thank you, Melanie. I confirm receipt of the attachment.

Best,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001
Home office phone#: 410-696-2236 (M, T, R, F)
Office phone#: 202-393-3903 x.117 (W)
f. 202-393-3906
alkoster@lewisharrison.com
https://lewisharrison.com/

From: Bolden, Melanie [mailto:bolden.melanie@epa.gov]
Sent: Tuesday, May 22, 2018 11:23 AM
To: Ana Koster
Cc: OPP AD Ombudsman; Fuller, Demson
Subject: Completed Action: EPA Reg. No. 73139-3

Hi Ms. Rodriguez-Koster,

Please see the attached completed action for EPA Reg. No.73139-3. The CSF Notification was accepted. **Please reply to this email, confirming its receipt and that you were able to view the attachment.** If you have any questions or concerns, please feel free to contact me.

Melanie Bolden
Environmental Protection Specialist
US Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division
Regulatory Management Branch II
(703)-347-0165

Product ingredient source information may be entitled to confidential treatment

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W. Suite 505
Washington, DC 20001
telephone 202.393.3903
fax 202.393.3906

May 7, 2018

VIA ELECTRONIC SUBMISSION (EPA PSP)

Document Processing Desk [NOTIF]
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTENTION: **Demson Fuller**
Product Manager, Team 32

SUBJECT: **Diklor G (EPA Reg. No. 73139-3)**
Formulation Notification per PR Notice 98-10

Dear Mr. Fuller:

As agent for Sabre Oxidation Technologies, Inc. ("Sabre"), I am submitting a formulation notification for their product, **Diklor G (EPA Reg. No. 73139-3)**. The purpose of this notification is to add two alternate registered sources of technical grade active ingredient. Note that the proposed alternate sources of technical grade active ingredient have the same active ingredient concentration and uses as the current approved sources.

Enclosed please find the following documents in support of this notification:

1. Application for Pesticide Notification, which includes a signed statement certifying compliance with PR Notice 98-10;
2. One (1) copy of the proposed Alternate Formulation #1;
3. One (1) copy of the proposed Alternate Formulation #2; and,
4. Completed Formulator's Exemption Form.

Thank you for your assistance with this application. If you have any questions about this submission, please call me at 202-393-3903 x. 117 or e-mail me at alkoster@lewisharrison.com.

Sincerely,

Ana Rodriguez-Koster
Agent for Sabre Oxidation Technologies, Inc.

cc: Sam Eltomi, Sabre Oxidation Technologies, Inc.

Please read instructions on reverse before comp g form. Form Appro OMB No. 2070-0060, Approval expires 05-31-98

EPA United States Environmental Protection Agency Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other: Notification

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
73139-3	**Demson Fuller**	☒ None ☐ Restricted
4. Company/Product (Name) **Diklor G**	PM# **Team 32**	

5. Name and Address of Applicant *(Include ZIP Code)*
Sabre Oxidation Technologies, Inc.
1891 New Scotland Road
Slingerlands, NY 12159
PLEASE DIRECT ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW
☐ *Check if this is a new address*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name_____

Section - II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

NOTIFICATION TO ADD TWO (REGISTERED) ALTERNATE SOURCES OF ACTIVE INGREDIENT

Notification to add Two (Registered) Alternate Sources of Active Ingredient in Accordance With PR Notice 98-10

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature:_____ Date: May 7, 2018

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic: ☐ Glass ☐ Paper ☐ Other (Specify)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Ana Rodriguez-Koster, Lewis and Harrison, LLC 122 C St., NW Suite 505 Washington, DC 20001	**Agent for Sabre Oxidation Technologies, Inc.**	**(202) 393-3903 ext. 117**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title:	
	Agent for Sabre Oxidation Technologies, Inc.	
4. Typed Name **Ana Rodriguez-Koster, Lewis & Harrison, LLC**	5. Date **5/7/2018**	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete **White- EPA File Copy (original) Yellow- Applicant Copy**

12/12

NEW APPLICATIONS

DATE: 10-26-2012

FILE NUMBER: 73139-G

FEP (OPPIN ENTRY) GM-LV NOV 27 2012
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: _____
(Initial & date)

FILE ROOM: _____
(Initial & date)

✓ ASSIGN TO PM 32 (NO DATA)

____ JACKET TO SHELF (DATA)

Material Sent for Data Extraction

Reg. # 73139-3

Description: _____

☐ Material(s) Sent to Data Extraction Contractors:

- ☒ New Stamped Label Dated 1/28/14
- ☐ Notification Dated _____
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☐ Decision #: 472355

☐ Other Action/Comments: _____

_____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: J. Pyne

Phone: 703-347-0213 Division: AD

Date: 2/6/14

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
73139-3	JAN 29 2014

Term of Issuance:
Conditional

Name of Pesticide Product:
DIKLOR G Chlorine Dioxide Sterilant Precursor

NOTICE OF PESTICIDE:
x Registration
__ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Sabre Oxidation Technologies
2642 Marco Avenue
Odessa, TX 79762

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec. 3(c)(7)(B), provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. A one year study is required to satisfy the storage and stability and corrosion characteristics requirements (Guidelines 830.6317 and 830.6320). You have 18 months from the date of registration to provide these data.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

Signature of Approving Official:

Demson Fuller
Product Manager Team 32
Regulatory Management Branch
Antimicrobials Division (7510P)

Date:
JAN 29 2014

EPA Form 8570-

For use only by:

- Federal On-Scene Coordinators (FOSCs) and contractors and other trained federal/state/local response personnel under the FOSC's supervision;
- Trained U.S. Military personnel and contractors under their supervision;
- Persons who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) following completion of the required training.

Under the terms and conditions of this product's registration, this product may only be sold or distributed by the registrant directly to the persons identified above.

DIKLOR ™G Chlorine Dioxide Sterilant Precursor

SPORICIDAL DECONTAMINANT for INACTIVATION of *Bacillus anthracis* SPORES on PRECLEANED, HARD, NON-POROUS and POROUS SURFACES

DIKLOR ™G Chlorine Dioxide Sterilant Precursor is a sporicidal decontaminant that inactivates *Bacillus anthracis* spores on precleaned, hard, nonporous and porous surfaces at certain sites when used in accordance with all precautions and directions specified on this label and in the attached DIKLOR ™G Chlorine Dioxide Sterilant Precursor Fumigation Manual(Fumigation manual).

ACTIVE INGREDIENT:	
Sodium Chlorite ----------	25.0%
OTHER INGREDIENTS:----------	75.0%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

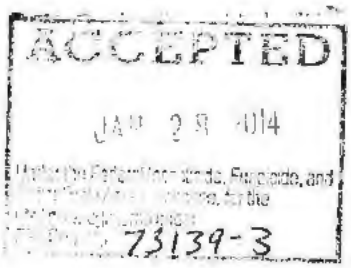
DANGER

SEE (SIDE) (BACK) PANEL FOR ADDITIONAL

PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg. No. 73139- 3
EPA Est. No.----------

Sabre Oxidation Technologies
2642 Marco Avenue
Odessa, TX 79762
Emergency Phone Number
1-800-222-1222



FIRST AID	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or physician for treatment advice.
IF SWALLOWED	Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor immediately for treatment advice.
NOTE TO PHYSICIAN: Probably mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Irritating to nose and throat. Do not breathe dust or vapors. Do not get in eyes, on skin or clothing. Do not handle with bare hands. Wear protective eyewear (goggles or face shield), clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse. Other chemical may be co-located for this process, refer to fumigation manual and respective Material Safety Data Sheet for chemical specific details.

PPE REQUIRED FOR PROTECTION FROM *BACILLUS ANTHRACIS* SPORES

When applying the product to areas contaminated with *Bacillus anthracis* spores, wear the personal protective equipment (PPE) described in this product's Fumigation Manual, the Fumigation Management Plan, or the Remediation Action Plan or equivalent plan.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS
Dry DIKLOR G is a strong oxidizing agent. Only mix into or dilute with water or non-oxidizable materials. Mixing with acids or other chemicals may start a chemical reaction with the generation of heat liberation of a hazardous gas (chlorine dioxide), and possible fire or explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty rags or any other foreign matter. Contact with acids may release toxic gas. Use only clean, dry utensils when handling.

EMERGENCY HANDLING
In case of contamination or decomposition, do not reseal container. If possible, isolate container in an open and well-ventilated area. Flood with large volumes of water. If fire occurs, extinguish fire by applying large volumes of water. Cool any unopened drums near the fire by spraying with water.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
STORAGE: Keep product dry in tightly closed container when not in use. Do not drop, roll or skid drum. Keep upright. Always replace cover. Store this product in a cool, dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water. Do not reuse empty container.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:
Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Offer for reconditioning, if appropriate. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

See the accompanying DIKLOR G Chlorine Dioxide Sterilant Precursor Fumigation manual for this product for complete use directions and safety precautions for inactivating *Bacillus anthracis* (anthrax) spores on porous and nonporous surfaces. The Fumigation manual contains fumigation specific chemical requirements and specifications in Section III, part D. Fumigation dosage concentration and time are in Section III, part N. This product will be used to create a chlorine dioxide solution at a concentration level of approximately 0.1 – 0.3 % through the controlled reaction of hydrochloric acid (15 percent), sodium hypochlorite (10 to 12 %), and sodium chlorite (%), or a prescribed on label. During the fumigation, a minimum temperature of 70° F, minimum Rh of 70 percent, and either (a) a minimum ClO_2 concentration of 500 parts per million by volume (ppm_v) or (b) a minimum ClO_2 concentration of 3,000 parts per million by volume (ppm_v) must be achieved. The minimum CT clock value of at least 9,000 ppm_v must be conducted at all monitoring locations throughout the duration of either 12 hours or 3 hours fumigation process.

For use only by:

- Federal On-Scene Coordinators (FOSC) and contractors and other trained federal/state/local response personnel under the FOSC's supervision;
- Trained U.S. Military personnel and contractors under their supervision;
- Persons who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) following completion of the required training.

Under the terms and conditions of this product's registration, this product may only be sold or distributed by the registrant directly to the persons identified above.

DIKLOR ™G Chlorine Dioxide Sterilant Precursor – Fumigation Manual

Sabre Oxidation Technologies
2642 Marco Avenue
Odessa, TX 79762
Emergency Phone Number
1-800-222-1222

SPORICIDAL DECONTAMINANT for INACTIVATION of *Bacillus anthracis* SPORES on PRECLEANED, HARD, NON-POROUS and POROUS SURFACES

DIKLOR ™G Chlorine Dioxide Sterilant Precursor is a sporicidal decontaminant that inactivates *Bacillus anthracis* spores on precleaned, hard, nonporous and porous surfaces at certain sites when used in accordance with all precautions and directions specified on the label and in this Fumigation Manual.

ACTIVE INGREDIENT:
Sodium Chlorite ---------- 25.0%
OTHER INGREDIENTS:---------- 75.0%
TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE (SIDE) (BACK) PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg. No. 73139- 3
EPA Est. No.----------

Sabre Oxidation Technologies
2642 Marco Avenue
Odessa, TX 79762
Emergency Phone Number

TABLE OF CONTENTS

I. GENERAL APPROACH TO FUMIGATION AND REMEDIATION

The objective of chlorine dioxide (ClO_2) fumigation is to effectively decontaminate buildings and contents contaminated or potentially contaminated with *Bacillus anthracis* spores on pre-cleaned, hard, porous and non-porous surfaces under operating conditions that protect site workers, the surrounding community and the environment.

Each fumigated building or subpart thereof must be properly tented or sealed and subjected to negative pressure by extraction of building air though negative air units (NAUs). The ClO_2 gas in extracted air is removed by means of an emission control system containing activated carbon cells. Specified temperature and relative humidity (Rh) conditions are to be achieved within the treatment zone prior to the introduction of ClO_2 gas. During fumigation, operational parameters are monitored at an appropriate number of co-located temperature, Rh, and ClO_2 gas sampling points. At the end of the specified time period for fumigation, the addition of ClO_2 gas is terminated and natural decay of the gas within the building begins. Where necessary, the decay process is accelerated by the addition of alkaline sodium sulfite, hydrogen peroxide, or erythobic acid solution to the process liquid loop. Decay of ClO_2 gas in the building decay continues until such time that ClO_2 concentration levels at all monitoring points have fallen below the Occupational Safety and Health Administration (OSHA) eight-hour time-weighted average (TWA) permissible exposure level (PEL) of 0.1 parts per million by volume (ppm_v), at which time the building may be re-entered by fumigation personnel.

The user of this product shall develop a site-specific Fumigation Management Plan (or Remediation Action Plan or equivalent) that follows these label instructions and takes into account site-specific information such as the size of the structure, materials of construction, contents, conditions, surrounding community particulars, as well as biological efficacy plan that may include biological indicators, and environmental sampling, etc.

II. PERSONAL PROTECTIVE EQUIPMENT (PPE) REQUIREMENTS

A. Respirator Requirements

When a respirator is required for use with this product:

- The respirator must be fit tested and fit checked using a program that conforms with OSHA's requirements (see 29 CFR Part 1910.134)
- The respirator user must be trained using a program that conforms with OSHA's requirements (see 29 CFR Part 1910.134)
- The respirator user must be examined by a qualified medical practitioner to ensure the physical ability to safely wear the style of respirator to be worn.
- The respirator must be maintained according to a program that conforms with OSHA's requirements (see 29 CFR Part 1910.134)

B. Other Protective Equipment

- Protective clothing—long sleeve shirt, long pants, shoes plus socks
- Gloves—specify appropriate type
- Protective eyewear or face shield

C. **PPE Required for Protection from *Bacillus Anthracis* Spores**

- When entering areas contaminated with *Bacillus anthracis* spores, wear the personal protective equipment (PPE) described in this product's Fumigation Manual, the Fumigation Management Plan, or the Remediation Action Plan or equivalent plan.

III. DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

A. Site Preparation

To the extent feasible, remove debris, non-reusable items and water-soaked materials. Eliminate sources of moisture ingress (e.g., roof or window leaks, damaged plumbing, etc.) that may contribute to water damage and/or mold growth. Open enclosed spaces (e.g., closets, drawers, cabinets, etc.) to allow maximum exposure to the ClO_2 gas during fumigation.

B. Building Containment

Tent (encapsulate) the building undergoing fumigation completely with a material demonstrated to be impervious to ClO_2 gas, or effectively seal the building through utilization of sealing materials such as tape, caulking, etc. in all external cracks, crevices, or building openings, through which ClO_2 might escape during fumigation.

C. Negative Air Pressure and Emission Control

For Structures of up to 17,000,000 cubic feet

Contain ClO_2 gas in the building through use of a negative air pressure system designed to maintain a slight negative pressure on the internal walls and ceiling of the building during fumigation operations. Achieve negative pressure by removing building air through two negative air units (NAUs). Locate the NAUs on opposite sides of the building where possible. The systems should be redundant in that each NAU should maintain a negative pressure on the building during times when the second NAU is shut down.

Monitor negative pressure through use of a pressure differential monitor (e.g., MAGNEHELIC® Gauge) installed on each NAU system. Conduct a negative air balance test before fumigation to demonstrate the ability of each NAU system to independently maintain a negative pressure on the building. Achieve a target negative pressure level during fumigation of -0.005 inches of water column or greater.

Air being removed from the building during fumigation to create negative pressure will contain residual ClO_2 gas. A treatment train is necessary to remove ClO_2 prior to discharging the extracted air to the surrounding environment. Provide each NAU with a gas scrubbing treatment train that consists of: (1) an induced draft fan; (2) vapor phase carbon cell; or a wet reducing scrubber in series with a vapor phase carbon cell; and (3) a means to monitor airflow, pressure differential and gas emission levels.

During fumigation operations, monitor the treated building air exiting the carbon cells to identify potential "breakthrough" of ClO_2 gas, which is indicative of exhaustion of the carbon cell media. Monitor potential breakthrough by placement of an extractive ClO_2 gas sample point at both the inlet and outlet to the scrubber treatment train. Collect samples from the outlet sample port on a continuous basis.

Pause the fumigation process immediately should breakthrough be observed until the cause of breakthrough is ascertained and corrective measures are implemented as necessary. Utilize corrective measures including one or more of the following, depending upon the situation: (1) reduce the amount of extraction air coming into the carbon cell; (2) shut the affected NAU down; (3) switch all air removal requirements to the unaffected NAU; (4) terminate any further ClO_2 gas additions to the building; and/or (5) convert the gas emitters to scrubbers to expedite removal of residual ClO_2 from the building.

Provide standby electrical generation power to provide power to critical fumigation systems (including the NAUs) should utility power to a fumigation site be interrupted at any time.

D. Chlorine Dioxide Generation

Generate ClO_2 solution in a Sabre Companies LLC (Sabre) mobile ClO_2 generation system that produces ClO_2 solution at a concentration level of approximately 1,000 – 4,000 ppm percent through the controlled reaction of hydrochloric acid (15 percent), sodium hypochlorite (10 to 12 percent) and sodium chlorite (25 percent, DiKlor G Sodium Chlorite Solution, USEPA Registration Number 73139-3) or as prescribed generation method on the label.

E. Chlorine Dioxide Distribution

Pump the liquid ClO_2 solution from the generator to gas "emitter(s)" strategically located around or inside the building. The emitter(s) remove ClO_2 gas from the ClO2 solution into the air stream flowing from the building, through the emitter(s) and back into the building. Allow depleted ClO_2 solution to flow back to the generator in a flow loop where it can be "recharged" to its initial concentration level and used again. Continue adding ClO_2 gas to the building until the target concentration is achieved and/or maintained in the desired range.

Locate the ClO_2 emitter(s) based on building configuration and location of existing Air Handler Units (AHUs). Use the building air distribution ductwork and diffuser system, as necessary, to distribute gas throughout the building treatment area. Design the number of emitters in sufficient quantity to deliver the desired concentration of ClO_2 gas to the entire structure undergoing fumigation. Use supplemental mass transfer fans where necessary in the building to assist in mixing and dispersion of the gas.

F. Chlorine Dioxide Removal

At the conclusion of fumigation, allow residual ClO_2 gas remaining in the building to decay naturally; alternatively, if quicker removal of ClO_2 is desired, convert the gas emitters into active gas scrubbers. Conversion of the ClO_2 gas emitters into ClO_2 gas scrubbers is accomplished by adding an alkaline sodium sulfite solution, an alkaline peroxide solution or an alkaline Erythorbic acid solution to the liquid ClO_2 solution process flow loop. Circulate this solution to the emitters so that ClO_2 gas is removed from the building when air is drawn through the emitters.

G. Temperature and Rh Control

Bring the building to a minimum temperature of 70° Fahrenheit (F) for at least one hour at all temperature monitoring points before introducing ClO_2 gas into the building. Control temperature through use of the building's existing heating, ventilation and air conditioning (HVAC) system or through use of portable heat generation or cooling devices. Operate building AHUs in full recirculation mode with no outside fresh air intake to help achieve the desired temperature level before fumigation.

Bring the building to a minimum Rh value of 70 percent for at least one hour at all Rh monitoring points before introducing ClO_2 gas into the building. If necessary to achieve and maintain the Rh level above 70 percent, utilize the emitters as humidifiers by controlling the temperature of water in the circulation loop and adjusting that temperature through use of steam coils, or cooling the water through a shell and tube heat exchanger. Make every reasonable effort to limit the development of a condensing atmosphere within the building during fumigation.

H. Chemical Storage

Store precursor chemicals in 55-gallon drums, 275-gallon totes or portable storage tanks. The quantity is dependent on the size of the building being fumigated. Make provisions for storage of the three ClO_2 precursor chemicals and neutralization chemicals (e.g., 25 percent sodium hydroxide, 36 percent sodium bisulfite, 50 percent hydrogen peroxide, or Erythorbic acid; note: type and quantity dependent on active scrubbing solution media chosen). Store all precursor and neutralization chemicals within secondary containment areas using proper segregation principles to prevent accidental mixing of reactive materials (e.g., store hydrochloric acid within a separate containment basin away from sodium chlorite and sodium hypochlorite).

I. Dehumidification

Dehumidify the building promptly after completion of ClO_2 gas removal to lower the relative humidity level of building air to at least 60% to facilitate drying of internal building surfaces to prevent growth of mold and mildew post fumigation. Confirm first that ClO_2 levels have fallen below the OSHA TWA PEL standard of 0.1 ppm_v at all monitoring locations within the building. Utilize the fumigated building's existing HVAC system to facilitate dehumidification where possible.

Continue the dehumidification process until such time that the moisture content of various types of building materials such as wood, drywall and masonry reach desired levels. Use a Moisture Encounter Meter where appropriate to measure the moisture content at various locations inside the building to confirm the effectiveness of the dehumidification process.

J. Process Wastewater

Store wastewater generated by the fumigation process in a dedicated on-site storage tank. Collect and analyze representative samples of the wastewater for purposes of waste profiling. If the wastewater is determined to be non-hazardous, dispose of into the sanitary sewer system if allowed by the local publicly owned treatment works. Otherwise, send off-site to a permitted, non-hazardous wastewater treatment facility.

K. Ancillary Equipment

Provide standby electrical generation power to provide power to critical fumigation systems should utility power to a fumigation site be interrupted at any time.

L. Equipment Testing

Test all key fumigation system components as they are installed to ensure that all subsystems will operate as designed.

Before commencing the fumigation, conduct a low-level "pulse" test in which all subsystems are simultaneously challenged as if it were the actual fumigation, with the exception that significantly lower ClO_2 concentration levels are used (i.e., 200 to 500 ppm_v) than those used during the actual fumigation process and ClO_2 is introduced into the building for a much shorter duration (i.e., 15-30 minutes). Design and conduct the test such that all elements that support the fumigation are proven functional, operational and effective.

During the low-level pulse test, bring environmental conditions inside the building to target levels and verify that all equipment is operating and functioning properly. Also verify that data collection devices and chemical fluid and gas sampling operations are functioning as designed. Finally, assess the exterior of the building with handheld ClO_2 monitors to make sure there are no significant gas leaks.

M. Fumigation Operation Sequencing

Perform fumigation activities in the following operational sequence to ensure safety and efficacy of the process.

Task Number	Task Description
1	Verify spill containment supplies are in place
2	Verify necessary chemical inventory is in place
3	Verify acceptable meteorological conditions exist
4	Conduct pre-fumigation safety meeting
5	Verify Emergency Response Team is in place
6	Verify Operations Team is in place
7	Verify building AHUs are operating
8	Verify Mass Transfer mixing fans are operating (when needed)
9	Initiate NAU operation
10	Achieve desired building negative pressures
11	Initiate liquid flow loop water circulation
12	Initiate emitter blower operation
13	Achieve desired temperature and Rh levels
14	Turn off all lights in building
15	Confirm all personnel are out of building
16	Initiate ClO_2 generation
17	Initiate ClO_2 concentration "ramp-up"
18	Initiate internal and external ClO_2 gas sampling
19	Achieve minimum desired ClO_2 concentration to start CT clock
20	Maintain ClO_2 concentration above target level
21	Achieve desired CT clock value at all monitoring locations
22	Terminate ClO_2 generation
23	Initiate active ClO_2 scrubbing (when needed)
24	Terminate scrubbing operations
25	Shut-down emitters and liquid process loop
26	Terminate gas sampling when $ClO_2 < 0.1$ ppm_v
27	Initiate building dehumidification
28	Conduct building inspection entry
29	Turn on lights in building
30	Terminate building dehumidification
31	Turn off AHUs, fans and NAUs

N. Operational Objectives

Achieve a minimum temperature of 70° F, minimum Rh of 70 percent, and either (a) a minimum ClO_2 concentration of 500 parts per million by volume (ppm_v) or (b) a minimum ClO_2 concentration of 3,000 parts per million by volume (ppm_v) at all monitoring locations to start the concentration by time (CT) building exposure clock.

Conduct fumigation with a minimum duration of either (a) twelve (12) hours or (b) three (3) hours that achieves a minimum CT Clock value of at least 9,000 ppm_v-hours at all monitoring locations.

O. Relative Humidity Monitoring

Monitor Rh at an appropriate number of co-located building locations through use of HOBO® Model U12-011 TEMP/RH Data Loggers or equivalent. The instrument has a measuring range of 5 to 95 percent with an accuracy of ± 2.5 percent. Take measurements at 5-minute intervals during the conditioning, fumigation and aeration phases of the process. Obtain a local readout of Rh readings by connecting the data loggers to a personal computer (PC) via USB, Cat 5 data cable or fiber optic cable from the various monitoring locations. Log data in the monitor during fumigation and download for manipulation following fumigation.

P. Temperature Monitoring

Monitor temperature at an appropriate number of co-located building locations through use of HOBO® Model U12-011 TEMP/RH Data Loggers. The instrument has a measuring range of -4 to 158° F with an accuracy of ± 0.63° F. Take measurements at 5-minute intervals during the conditioning, fumigation and aeration phases of the process. Obtain a local readout of temperature readings by connecting the data loggers to a PC via USB Cat 5 data cable or fiber optic cable from the various monitoring locations. Log data in the monitor during fumigation and download for manipulation following fumigation.

Q. Chlorine Dioxide Monitoring

Monitor ClO_2 concentration levels by means of a composite sample collection system constructed of 3/8-in inside diameter high-density polyethylene (HDPE) tubing. HDPE tubing has been shown to be non-reactive with ClO_2. Run the tubing from an appropriate number of co-located monitoring locations inside the building to a central sampling manifold located outside the building. Have knowledgeable air-sampling technicians collect samples and deliver them to an on-site gas laboratory for analysis. Place a vacuum pump on the downstream side of the sampling manifold to move air through the system and return it to the building on a continuous basis such that the samples represent existing conditions within the building at the time they are taken.

Collect samples from the sampling manifold via impingement of two liters of air at a flow rate of 1.0 liter per minute through 15 milliliters of a strongly buffered pH 7 potassium iodide solution (modified OSHA Method ID126SGX). Once collected, analyze samples via amperometric titration, using a 0.1 normal sodium thiosulfate solution as the titrant (modified American Water Works Association Method 4500-ClO_2-E and modified 2-step version of same).

During ClO_2 ramp-up, collect samples at a select number of monitoring locations every 15 minutes until the minimum CT Clock start value is demonstrated at these locations. Once the minimum CT Clock start value has been established, collect samples at all monitoring locations every 30 minutes for the remainder of the fumigation. It is possible that additional samples may be required outside of the normal rotation sequence of one sample per half-hour. Reasons that could trigger increased sampling include abnormally low or high ClO_2 concentration readings, mechanical problems with the sampling pump or impingers, condensate in the sampling tubing, etc. Commence the use of an increased sampling frequency when necessary due to special circumstances and continue until the situation that initiated the problem is corrected.

R. CT Clock Monitoring

Start the CT clock when the desired minimum ClO_2 concentration level (either 500 or 3,000 ppm) is reached at all selected monitoring locations. Once started, accumulate CT exposure credit so long as the ClO_2 concentration level remains above the minimum established criteria value, as do temperature and Rh readings. Continue the fumigation until all monitoring locations have achieved a 9,000 ppm_v-hour minimum CT clock value. Place accumulated CT clock values on hold if the established minimum Rh, temperature and ClO_2 concentration values

are not maintained. Restart the CT clock during the next sampling period during which all three process variables are found to be in compliance with the prescribed minimum values.

S. Use Precautions

Conduct fumigation operations in a manner that protects both workers and members of the general public from exposure to fumigation process chemicals through implementation of specifically designed safety measures.

T. Worker Safety

Site-Specific Health and Safety Plan

Develop a site-specific Health and Safety Plan (HASP) to establish safe working and operating conditions for both fumigation preparation activities and fumigation operations. Prepare the HASP in accordance with applicable OSHA guidelines and regulations.

Health and Safety Training

Establish minimum health and safety training requirements for all personnel involved in fumigation operations. Do not allow workers to participate in, or supervise field activities until they have been trained to a level required by their job function and responsibility. Cover appropriate elements during initial training including: (1) names of personnel and alternates responsible for site safety and health; (2) safety, health and other hazards present on site; (3) proper use, care and maintenance of PPE; (4) work practices by which the worker can minimize risks from hazards; (5) safe use of engineering controls and equipment on site; (6) medical surveillance requirements, including recognition of symptoms and signs which might indicate over exposure to hazards; and (7) contents of the site HASP.

In addition to initial training, provide Hazard Communication (HAZCOM) and Respiratory Protection training. In HAZCOM training, provide information on the possible types of biological or chemical agent contamination present within a facility, as well as the chemical substances stored and generated on-site, including physical properties, fire and explosion data, reactivity data, health hazard data, emergency and first aid procedures, spill and leak procedures, etc. In Respiratory Protection training, provide information about the proper selection, fitting, use, care and maintenance of respirators, with an emphasis on specific respirators worn if responding to an emergency involving either a chemical release or a fire. Provide basic First Aid and CPR training to all personnel who might be involved in a response to a medical emergency on-site.

Provide an orientation briefing to individuals who are on-site for short periods of time performing limited tasks as either visitors or contractors, including an overview of the site-specific HASP and a discussion of the facility layout. Also make these individuals aware of evacuation notification procedures and alert them to the pre-determined emergency response Rally Points or places of safe refuge where they should report in the event of an emergency.

Post-Fumigation Building Re-Entry Requirements

Establish a post-fumigation building re-entry requirement that prohibits workers from re-entering the building in OSHA Level D protective equipment until such time that it has been demonstrated that the concentration of ClO_2 at all monitoring points has fallen to a level below the applicable OSHA TWA PEL standard of 0.1 ppm_v.

U. **Public Safety**

Coordination with Local Authorities

Coordinate in advance with local agencies responsible for providing emergency response services regarding the fumigation process and make them aware of facility information, potential chemical hazards and on-site response procedures so they will be prepared to effectively respond or assist should an emergency event occur. Where appropriate, conduct an on-site orientation session to familiarize authorities with the site as well as the potential emergency events and hazards associated with on-site chemical storage and ClO_2 generation events.

Site Emergency Planning

Conduct meetings on-site periodically to discuss project roles and responsibilities, site communication procedures, hazardous materials storage issues and potential hazards. The goal of these meetings should be to gain consensus with regard to roles and responsibilities during potential emergency events.

Site Security

Establish site security measures to prevent unauthorized entry to the site and secure the site perimeter during on-going fumigation preparation activities. Include site entry control procedures, personnel responsibilities, facility lighting requirements and emergency communication procedures.

Specialized Training

Provide specialized training to prepare site personnel to respond to a variety of potential emergency event scenarios that might occur during fumigation preparation activities or during the fumigation itself including a fire inside or outside the building, chemical spill and/or a release of a significant amount of the fumigant to the atmosphere during fumigation.

Emergency Response Supplies and PPE

Stage appropriate spill response supplies in location suitable for cleanup of hazardous materials being stored on-site in close proximity to the stored materials. Also stage a variety of PPE, including Self-Contained Breathing Apparatus, at appropriate locations for use in an emergency response to a potential hazardous material release.

Site Communications

Assign two-way radios to key personnel at the site. Two-way radios facilitate effective communication among all parties at the worksite and allow for careful monitoring of work tasks by individuals responsible for initiating and performing emergency response activities. Use separate channels for work being performed inside and outside the building so that individuals monitoring the work can effectively monitor tasks being performed in both locations simultaneously.

Surface and Ground Water Protection

Protect surface and ground water supplies by containing any chemical release that might occur within a secondary containment area and respond with absorbents and neutralizing agents stored on-site. Place impervious spill mats

in close proximity to storm drains in the vicinity of chemical storage areas where necessary. Deploy these mats immediately to cover drainage catch basins in the event of a chemical release from a primary storage vessel.

Site Evacuation Contingency Plan

Develop specific procedures to respond to a potential emergency response scenarios that might occur during fumigation preparation operations or the fumigation itself. Identify a Site Safety and Health Officer (SSHO) who is responsible for determining when on-site personnel should "Shelter-In-Place" or evacuate the site should an emergency evacuation of the site be contemplated.

V. Fire Response

Place fire extinguishers throughout the site, both inside and outside the building, for use in fighting an incipient-stage fire. Also, activate existing operational building fire suppression systems in the event of a fire inside the building.

In the event that a fire is detected either inside or outside the building, implement a series of predetermined response measures including the following:

- The individual who identifies the fire immediately alerts their Supervisor, the SSHO and the Emergency Response Coordinator (ERC) for the site.
- If the individual who identified the existence of the fire can immediately extinguish it with a local fire extinguisher without endangering themselves or others, they extinguish the fire while the ERC is assembling the on-site Emergency Response Team (ERT).
- The on-site ERT dons proper PPE and initiates emergency response activities. The ERT is provided with PPE as warranted by the nature of the fire
- Potentially affected electrical systems are deactivated as soon as possible if appropriate to prevent a spread of the fire.
- After donning appropriate PPE, the source and nature of the fire are investigated. If the fire is determined to be in its incipient stage, the ERT attempts to extinguish the fire. If a fire either inside or outside the building is determined to be beyond the incipient stage, the SSHO or ERC immediately requests the assistance of external emergency fire response authorities.
- The SSHO notifies all site workers to cease their activities, shutdown all process equipment and report to a designated location so that a "headcount" may be taken to account for all personnel.
- The SSHO determines if a site evacuation is necessary. If instructed to evacuate, personnel proceed to one of the designated Rally Points or to an off-site place of safe refuge.
- If the fire emergency also involves a release of hazardous materials, the release is addressed in accordance with the response measures outlined in Section 4.2.3 of this Plan.
- If necessary, based on the size and scope of the fire, the SSHO notifies appropriate external authorities and provides them with appropriate information about the fire.

W. **Chemical Spill Response**

Locate all storage vessels within secondary containment areas. Store incompatible materials within separate secondary containments. Place impervious spill mats near all storm water catch basins in the vicinity of chemical storage areas where necessary to prevent inadvertent discharge of chemicals through the storm drain sewer system in the event of a leak or other accidental release.

In the event that a hazardous material leak from a storage vessel or associated piping is detected, implement a series of predetermined response measures including the following:

- The individual who identified the release immediately alerts their Supervisor, the SSHO and the ERC for the site.
- The ERC assembles the on-site ERT, who don proper PPE and initiate response activities. The ERT is provided with PPE as warranted by the nature of the hazardous material release.
- After donning appropriate PPE, the source and nature of the release are investigated and the release is stopped at its source (if safe to do so). Spill mats are placed over storm drain catch basins to prevent discharge of spilled material to the storm water drainage system and/or to ground water where necessary. Any sources of ignition present in the area are also eliminated.
- If any personnel have been affected by the release, they are evacuated from the area of impact as soon as possible and first aid is administered as appropriate. If necessary, external medical emergency response authorities are summoned.
- Only members of the ERT involved in overseeing or performing emergency operations are allowed within the designated hazard area. If possible, the area is roped or otherwise blocked off. If a release cannot be immediately contained within a containment area, an isolation area is established around the spill, using sorbent and neutralizing materials.
- In the event a release breaches onsite secondary containment, the leading edge around the spill is contained with neutralizing agents and/or absorbents or other appropriate materials. Pumps may be employed to transfer spilled liquids to on-site waste tanks and for the removal of any liquid that may congregate at low points or depressions on surfaces.
- If the total amount of hazardous material released is less than the equivalent volume of 300 gallons, spill response materials and equipment located on-site are utilized to contain and collect the waste.
- Collected waste material is stored in secure storage containers for future disposal.
- If the amount of hazardous material released is greater than that which can be contained and collected for disposal by the on-site ERT, arrangements are made with an external contractor to respond to the site with adequate supplies and equipment to perform necessary clean-up operations.
- The SSHO determines if a site evacuation is necessary. If instructed to evacuate, personnel proceed to one of the designated Rally Points or to an off-site place of safe refuge.
- The SSHO notifies external emergency response authorities if deemed necessary by the size and scope of the release. External emergency response authorities will take appropriate actions if required to safeguard the surrounding community.

- Following the initial spill response, provisions are made to conduct a full environmental assessment to delineate impacted areas. Hazardous materials generated from a release are disposed of off-site in accordance with applicable laws and regulations.

X. Building ClO_2 Leak Detection and Repair

Perform ambient air monitoring during botb the low-level "pulse" test and the actual fumigation to identify leaks of ClO_2 gas from the building so that appropriate action may be taken in the event a leak is detected. Whenever possible, repair building leaks immediately using appropriate patching materials.

Dispatch teams of trained employees to the immediate perimeters of the building, and to the rooftop where appropriate, as soon as ClO_2 liquid begins flowing from the generator to the emitters. Initially assign at least two teams to building monitoring duties. Each team should consist of at least two individuals, each having had sufficient previous experience with ClO_2 to readily identify its characteristic odor in air.

Equip each monitoring team with a calibrated Industrial Scientific Gas Monitor with a ClO_2 sensor capable of detecting ClO_2 gas and reporting TWA readings for purposes of comparison with OSHA's eight-hour TWA PEL and the American Conference of Governmental Industrial Hygienists (ACGIH) recommended 15-minute TWA Short Term Exposure Limit (STEL). The OSHA PEL for ClO_2 is 0.1 ppm_v, and the ACGIH STEL is 0.3 ppm_v. Because the human olfactory response to ClO_2 has been shown through experience to be far more sensitive than any commercially-available hand-held monitoring technology, the primary objective of using the monitor is not to identify the presence of ClO_2 emissions, but rather to make sure that team members are not being exposed to concentrations of the gas that are in excess of prescribed standards and recommended threshold levels while they are performing their ambient monitoring and repair assignments. In the event that ClO_2 readings above the 0.1 ppm_v eight-hour OSHA standard or the 0.3 ppm_v 15-minute ACGIH STEL are registered by a monitor during fumigation, the team identifying the reading should leave the area where the elevated reading was identified and don appropriate respiratory protection before continuing work in the area. A full-face negative pressure respirator with combination P-100 filter/acid gas cartridges should be used for ClO_2 concentrations above an applicable exposure standard but less than 5 ppm_v. A self-contained breathing apparatus and appropriate skin protection should be used in any atmosphere containing more than 5 ppm_v of ClO_2.

Identify potential sources of ClO_2 emissions from the top and sides of the building and immediately perform any repairs and/or modifications necessary to eliminate or reduce emissions to the greatest degree possible. Also, communicate monitoring findings to the Project Manager so that operational changes and/or a shutdown of fumigation operations can be initiated immediately in the event that a leak cannot be effectively patched in a reasonable period of time. When a building leak cannot be quickly and effectively repaired, adjust operational parameters as necessary to mitigate the leak or terminate the fumigation process to eliminate exposure risk to the surrounding community.

Y. Adjustment of Operational Parameters

In the event a ClO_2 leak cannot be promptly repaired through use of available patching materials, adjust fumigation operating parameters, either temporarily or for the remaining duration of the fumigation, to prevent additional gas from escaping the building into the surrounding environment.

Increase the NAU fan speed upwards to increase the negative pressure level on the internal walls and ceiling of the building and/or decrease the target ClO_2 concentration level being applied to the building to lower the concentration of ClO_2 in air escaping through the leak.

Z. Termination of Fumigation Process

Should it be determined that a significant ClO_2 leak cannot be effectively repaired, nor can the magnitude of the leak be substantially mitigated through adjustment of operational parameters, terminate the fumigation process and take necessary measures to remove residual gas from the building.

Turn gas emitters into gas scrubbers through the addition of an appropriate neutralizing agent to the liquid ClO_2 flow loop. Circulate this solution from the generator to the emitters to remove ClO_2 from the building as air is drawn through the emitters.

AA. Post Fumigation Repair and Cleaning

Remove any remaining debris, non-reusable items and water soaked materials. Replace, repair or clean damaged areas of structure as needed.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND POLLUTION
PREVENTION

December 2, 2013

MEMORANDUM

SUBJECT: Review of Additional Efficacy Data Associated with Diklor™ G Chlorine Dioxide as a Sporicidal Decontaminant for *Bacillus anthracis* Spores

FROM: Stephen Tomasino, Ph.D., Senior Science Advisor *Stephen Tomasino*
Microbiology Laboratory Branch
Biological and Economic Analysis Division

TO: Mark Perry, Team Leader
Product Science Branch
Antimicrobials Division

Jaclyn Pyne
Regulatory Management Branch II
Antimicrobials Division

I have reviewed the additional efficacy data (laboratory) submitted by Sabre Oxidation Technologies (Company 73139) in support of the proposed sporicidal activity claim for Diklor™ G Chlorine Dioxide. The company is seeking a sporicidal decontaminant claim designed to inactivate the spores of *Bacillus anthracis* on pre-cleaned hard non-porous and porous surfaces. As stated in the August 1 memorandum to the Antimicrobials Division, the laboratory data provided in the Technology Evaluation Report: Evaluation of Chlorine Dioxide Generator –April 2006 support the product's sporicidal efficacy against virulent *B. anthracis*; however, additional data of this nature were recommended by MLB. To augment the data, the applicant provided the following documents: 1) Determining the Efficacy of Liquids and Fumigants in Systematic Decontamination Studies for *Bacillus anthracis* Using Multiple Test Methods (EPA/600/R-10/088, December, 2010) and 2) Systematic Investigation of Liquid and Fumigant

Decontamination Efficacy against Biological Agents Deposited on Test Coupons of Common Indoor Materials (EPA 600/R-11/076, August, 2011). The focus of this review is on the most relevant data set which is presented in the first document (EPA/600/R-10/088, December, 2010). The report provides product efficacy data using three sporicidal test methods. The data from all three methods and associated conclusions have been reviewed. Please see my comments and recommendations below:

Technical Review

Determining the Efficacy of Liquids and Fumigants in Systematic Decontamination Studies for *Bacillus anthracis* using Multiple Test Methods (EPA/600/R-10/088, December, 2010).

Background/Methodology.

- The document covers the evaluation of several sporicidal technologies, including gaseous chlorine dioxide (Sabre), to determine their efficacy against *B. anthracis* Ames spores. The evaluation was conducted by Battelle and funded and managed by EPA's Office of Research and Development. Staff from the Office of Pesticide Programs (OPP) contributed to the review of the test plan. Three standardized sporicidal efficacy methods accepted by OPP for registration of products with *B. anthracis* claims were used in the evaluation (see page 9 of the document – Test Procedures). Spores of virulent *B. anthracis* Ames and an acceptable surrogate, *B. subtilis*, were the test microbes. An EPA-approved Quality Assurance/Quality Control Test Plan was used to maintain a high level of documentation, auditing and reporting. In addition, biological indicators (BIs) were included in the fumigation tests. Sabre Technical Services provided the gas generator used in the chlorine dioxide study.

- The first method, AOAC method 966.04 (Sporicidal Activity of Disinfectants Test), requires testing on porcelain penicylinders and silk suture loops as nonporous and porous materials, respectively. For the second method, AOAC method 2008.05 (Quantitative Three Step Method), 5 x 5 mm glass coupons were used as test carriers. The third method, referenced here as iSOP, is a quantitative method developed by Battelle, in which product efficacy is determined by measuring the number of viable spores remaining on ceiling tile (porous), galvanized metal, and glass coupons following the contact time. The methods were modified for testing fumigants. All *B. anthracis* Ames and *B. subtilis* spore preparations used in all three methods were prepared according to the AOAC 966.04 by culturing on amended nutrient agar to yield a stock spore suspension of approximately 1 x 10^9 CFU/mL.

- The ClO_2-generating solution was prepared according to Sabre's instructions by mixing household bleach (5%-6% sodium hypochlorite), 6 N hydrochloric acid, 25% sodium chlorite (Sabre Clor25) and distilled water. Three levels of product concentration (high, medium and low) were employed in the study; however, for the purpose of this review, only the high efficacy level data (3000 ppmv) are relevant. A level of 3000 ppmv for 3

hr achieved a concentration x time (CT) of 9000 ppm-hr. Temperature for the decontamination was maintained in the range of 22°C ± 2°C, and the relative humidity (RH) was maintained at 75% ± 5%. The fumigant concentration was required to be within 10% of the target concentration.

Results.

- **AOAC 966.04**: See **Table 5.1** of the report for results – 3 hr at 3000 ppmv. Three 30-carrier tests were conducted against spores of *B. anthracis* and *B. subtilis* for each carrier type (porcelain and silk loops) for the 3 hr x 3000 ppmv condition. No positive carriers were recorded for this treatment, thus the data support sporicidal efficacy at the 9000 ppm hr level.
    - Note: OCSPP 810.2100 calls for 60-carrier tests when using a qualitative method for a *B. anthracis* claim (sporicidal decontaminant); however, due to the additional data provided with the two quantitative test methods below, this reviewer has determined the 30-carrier tests to be adequate.

- **AOAC 2008.05**: See **Table 5.2** of the report for results – 3 hr at 3000 ppmv. Three replications were conducted against spores of *B. anthracis* and *B. subtilis* on glass for the 3hr x 3000ppmv condition. Three treated and three control carriers were evaluated for each combination. Sporicidal efficacy was verified as log reduction values ≥6 were achieved for both microbes at the 9000 ppm hr level. Complete kill (no viable spores recovered) occurred during each test.

- **iSOP**: See **Table 5.3** of the report for results – 3 hr at 3000 ppmv. Three replications were conducted against spores of *B. anthracis* and *B. subtilis* on ceiling tile, galvanized metal, and glass for the 3hr x 3000ppmv condition. Five treated and five control carriers were evaluated for each combination. Sporicidal efficacy was verified as log reduction values ≥6 were achieved for both microbes on all surfaces at the 9000 ppm hr level. Complete kill (no viable spores recovered) occurred during all of these tests for porous and nonporous carriers.

- Note: The results for the biological indicator, *B. atrophaeus*, were negative for all tests. The spores were inoculated on stainless steel strips in Tyvek pouches and placed in the test chamber during exposure.

Conclusions

The current documentation (EPA/600/R-10/088, December, 2010) submitted by Sabre Oxidation Technologies in support of the registration of Diklor™ G Chlorine Dioxide satisfies the deficiencies in the laboratory data noted in the August 1, 2013 memorandum, and generally meet the testing recommendations outlined in OCSPP 810.2100. The data support the efficacy of the product at the 9000 ppm hr level against spores of *B. anthracis* on porous and nonporous surfaces. However, several additional questions and issues identified

in the previous review were not addressed by the applicant. I highly recommend that the Agency contact the applicant in an attempt to further document their responses prior to final approval of the efficacy evaluation. Feel free to contact me if you have any questions or concerns regarding this review. I can be reached at Tomasino.Stephen@epa.gov or by phone at 410-305-2976. Also, if requested, MLB will review the additional responses, if received, and the final product label.

cc: Susan Lawrence, MLB/BEAD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND POLLUTION
PREVENTION

August 1, 2013

MEMORANDUM

SUBJECT: Technical Review of the Sabre Oxidation Technologies Efficacy Data for Diklor™ G Chlorine Dioxide as a Sporicidal Decontaminant for *Bacillus anthracis* Spores

FROM: Stephen Tomasino, Ph.D., Senior Science Advisor Stephen Tomasino
Microbiology Laboratory Branch
Biological and Economic Analysis Division

TO: Mark Perry, Team Leader
Product Science Branch
Antimicrobials Division MJP 8/1/13

Per your request, I have reviewed the efficacy data package (submission #927289) submitted by Sabre Oxidation Technologies (Company 73139) in support of the proposed sporicidal activity claim for Diklor™ G Chlorine Dioxide. The company is seeking a sporicidal decontaminant claim designed to inactivate the spores of *Bacillus anthracis* on pre-cleaned hard non-porous and porous surfaces. For this review, I referred to the OCSPP Product Performance Test Guidelines (810.2100) for Sterilants (*B. anthracis* claims) for the current registration requirements. The efficacy data package is comprised of three studies related to the use of chlorine dioxide gas – two are field studies and one is an EPA-sponsored laboratory evaluation of chlorine dioxide under the Office and Research and Development – National Homeland Security Research Center's Technology Testing and Evaluation Program (TTEP). This review provides general observations and comments on the technical aspects of each efficacy study, and MLB's recommendations on how to proceed forward with this application as it related to the proposed label claims. The Fumigation Manual provides the Directions for Use – I referred to the section on Operational Objectives (page 8) in an effort to confirm application conditions.

Background. Under a series of EPA-approved crisis exemptions, chlorine dioxide gas gained significant prominence as a large-scale decontaminant during the anthrax clean-up efforts between 2002-2004. Chlorine dioxide gas is not stable as a compressed gas and therefore must be produced on-site. For example, the chemical was used to successfully remediate three major facilities, the Hart Senate Office Building, the U. S. Postal Service (USPS) – Trenton NJ Processing and Distribution Center, and the USPS Brentwood Processing and Distribution Center, Washington, DC. Pesticidal products containing either sodium chlorite or stabilized chlorine dioxide are usually mixed with another "reactive" chemical, usually an acid, to produce chlorine dioxide in a liquid or gaseous state. The liquid chlorine dioxide is then applied to hard surfaces with a sponge or mop or as a coarse spray. Chlorine dioxide gas may also be generated on site and released into a sealed treatment area where it remains for several hours before being removed. After the treatment is completed, the chlorine dioxide gas is neutralized with sodium bisulfite.

Technical Review

General Overview. The sporicidal efficacy evaluation of Diklor™ G Chlorine Dioxide provided by the applicant is not based a conventional data collection process for product registration with a *B. anthracis* claim; rather, the applicant relies on data collected from three independent events (i.e., studies). The package provides efficacy data from both the field and laboratory environments. A high degree of quality control and federal oversight were implemented for each study. Two of the three studies are based on actual clean-up efforts of anthrax-contaminated sites (per conditions specified under a crisis exemption). The three studies are:

- Chlorine Dioxide Gas Fumigation for the Inactivation of *Bacillus anthracis* Spores – USPS Curseen-Morris Processing and Distribution Center, Washington, DC (May 2003)
- Chlorine Dioxide Gas Fumigation for the Inactivation of *Bacillus anthracis* Spores – USPS Trenton Processing and Distribution Center, Hamilton Township, NJ (January 2004)
- EPA ORD/NHSRC Technology Evaluation Report – Evaluation of Chlorine Dioxide Gas Generator (April 2006)

A review of each study is provided below:

A. Chlorine Dioxide Gas Fumigation for the Inactivation of *Bacillus anthracis* Spores – USPS Curseen-Morris Processing and Distribution Center, Washington, DC:

The Curseen-Morris Processing and Distribution Center was fumigated with ClO_2 gas on December 14-15, 2002. The target microorganism was *B. anthracis* and surrogates were *B. subtilis*, *B. stearothermophilus*, and *B. atrophaeus*. The surrogates were introduced into the test environment as biological indicators (BI). The concentration levels of chlorine dioxide were maintained above 500 ppmv; the peak concentration was 1907 ppmv while the average was 1450 ppmv. The temperature was maintained above 75°F. With the exception of one location, the relative humidity was maintained above 75%. Concentration × Time (CT) values were used to monitor the dosage of chlorine dioxide gas. A dose clock value necessary to achieve 9000 ppmv-

hr was the goal. BI strips and a series of environmental sampling assays were used to determine the efficacy of the treatment.

Of the 4,902 BI strips analyzed, 1,130 were at a 4-log level while 3,772 were at a 6-log level. Each of the 1,130 4-log spore strips was deemed negative following exposure to chlorine dioxide gas. Fifty-seven of the 3,772 6-log spore strips were deemed positive following exposure to chlorine dioxide gas. To determine the presence of viable *B. anthracis* spores, wipe sampling was performed on smooth surfaces. All 2,152 wipe samples were found to be negative for *B. anthracis*. Vacuum samples were taken from irregular surfaces – each of the 1,742 HEPA samples was negative. Wipe-swab samples were collected from cracks and crevices. Of the 338 wipe-swab samples, all were negative. Furthermore, air samples were taken from 39 locations throughout the building, each of the 601 air samples was negative.

- Comments:
  - The report does not specify Good Laboratory Compliance – 40 CFR Section 160
  - The production lot/batch is not defined. The chlorine dioxide solution was made on-site using proprietary equipment.
  - Based on the information provided in this study, it is not possible to know the level of the starting population of *B. anthracis* spores in the test environment, thus an estimate of log kill cannot be calculated. Provide a summary of this information if available.
  - The identity of the surrogate used in the BI strips was not identified – this must be provided by the applicant. Furthermore, the applicant must justify the appropriateness of the surrogate species.
  - The applicant must explain the impact of the 57 positive 6-log BI strips.
  - The applicant must fully explain how the conditions in the study relate to the operational conditions described in the manual, including the CT level.
  - The applicant must identify both porous and non-porous substrates sampled in this study to support registration claims.

B. Chlorine Dioxide Gas Fumigation for the Inactivation of *Bacillus anthracis* Spores – USPS Trenton Processing and Distribution Center, Hamilton Township, NJ:

The Trenton Processing and Distribution Center in Hamilton Township, NJ was closed in October 2001 following contamination with spores of *B. anthracis*; nearly all areas of the facility were contaminated. In October 2003, the facility was treated with chlorine dioxide gas – this study provides the outcome of the remediation process. The concentration levels of chlorine dioxide were maintained above 500 ppmv; the peak concentration was 1424 ppmv with an average of 1271 ppmv. The temperature was maintained above 75°F during fumigation. BI strips, Stericharts (a series of five spore strips) and surface sampling were predominantly used to determine the efficacy of the treatment.

BI strips (4,105) containing 6-logs of *B. atrophaeus* spores (the selected surrogate) were placed randomly throughout the facility in a grid pattern with at least one Sterichart per grid. A total of 269 Stericharts (1,345 total strips) were used. An additional 389 spore strips were placed in

"hard to reach" areas. Following treatment, 38 (0.92%) of the 4,105 spore strips were positive. Five (0.52%) of the Stericharts were positive. Three (0.77%) of the 389 spore strips placed in "hard to reach" areas were positive. In addition, a total of 4,044 environmental surface samples were collected – all were determined to be negative for *B. anthracis.*

- Comments:
  - The report does specify Good Laboratory Compliance – 40 CFR Section 160
  - The production lot/batch and associated chemistry formulation of sodium chlorite is not provided. The chlorine dioxide solution was made on-site using proprietary equipment.
  - Based on the information provided in this study, it is not possible to know the level of the starting population of *B. anthracis* spores in the test environment, thus an estimate of log kill cannot be calculated.
  - The identity of the surrogate used in the BI strips was identified; however, the applicant must justify its use as an appropriate surrogate.
  - The applicant must explain the impact of the positive BI strips and Stericharts.
  - The applicant must fully explain how the conditions in the study relate to the operational conditions described in the manual, including the CT level.
  - The applicant must identify both porous and non-porous substrates sampled in this study to support registration claims.

C. EPA's Technology Evaluation Report: Evaluation of Chlorine Dioxide Generator – April 2006

The Sabre chlorine dioxide gas generator was evaluated by Battelle per ORD's NHSRC TTEP under laboratory conditions for efficacy against spores of *B. anthracis* (Ames) and two surrogates (*B. subtilis* and *G. stearothermophilus*). Several indoor test surfaces, both porous and non-porous, were evaluated. A comprehensive Quality Assurance (QA) test plan was prepared specifically for this project; the plan was approved by EPA and was included in the submission. Due to EPA's previous approval of the QA test plan, a review during this request was not conducted. A bench scale generator was used to generate the chlorine dioxide gas – the gas was pumped into a glove box measuring 71 cm wide × 59 cm deep × 74 cm high. Real time monitoring of the gas was used to ensure a total treatment time of 3 hours at 3000 ppm gas in order to achieve a CT of 9000. BI strips containing 6 logs of *B. subtilis* spores were also used to monitor efficacy. A single study was performed. The data were generated with a well-developed quantitative assessment following an internal Battelle test protocol. The mean CT value across all runs was 9205 ppm-hr. Log kill of spores was above 6 for all coupons and microbes. All BI strips were negative.

- Comments:
  - The report specifies compliance to Good Laboratory Standards – 40 CFR Section 160
  - The report does not provide details of the quantitative methodology used by Battelle to measure product efficacy – a literature citation or a copy of the method should be provided.

- The applicant specifies the use and identity of a virulent strain of *B. anthracis* (Ames), surrogates and *Bacillus* species for the BI strips.
- The applicant must fully explain how the conditions in the study relate to the operational conditions described in the manual, including the CT level.
- The data in this study may be used to support the requirements for a *B. anthracis* claim.
- It appears only one production lot of the product was prepared – please verify or clarify.

Conclusions

- The data package submitted by Sabre Oxidation Technologies for Diklor™ G Chlorine Dioxide does not fully meet the requirements specified in the Product Performance Test Guidelines for Sterilants – 810.2100 (2012) for a sporicidal decontaminant with a *B. anthracis* claim. However, the efficacy data provided could be used to support a crisis exemption, if necessary. The applicant should carefully review the Test Guidelines and if necessary contact EPA for clarification of the requirements. This reviewer assumed that Diklor G Chlorine Dioxide did not have an existing sterilant claim, thus options for a stand-alone *B. anthracis* claim were only considered. The guidelines provide options for qualitative and quantitative testing for gases; this submission is more closely aligned with quantitative testing. The section of the guidelines pertaining to the EPA's requirements for a *B. anthracis* claim is provided in Attachment 1. The requirements include:
  - Use of a well developed quantitative sporicidal test method under laboratory conditions
  - Use of virulent *B. anthracis* or an acceptable surrogate
  - The laboratory studies should include three product samples, representing three different batches
  - The coupon material should be representative of the surface types that appear on the product label
  - Meet a mean 6-log reduction performance standard
  - In addition to the three laboratory tests, a simulated use test (in a room or large warehouse) is required.
  - All tests must be conducted in accordance with GLPs per 40 CFR part 160 or in a federal laboratory with an appropriate QA test (project) Plan.
- The laboratory data provided in the Technology Evaluation Report: Evaluation of Chlorine Dioxide Generator adequately supports the product's sporicidal efficacy against virulent *B. anthracis* and surrogates; however, additional data of this nature will be required. Two additional batches or runs of Diklor G Chlorine Dioxide should be tested according to the provided QA test plan or a new/revised QA test plan. The applicant may consider testing only a surrogate and a reduced number of carrier types -- EPA must approve the selection of the surrogate, the coupon types and study design in advance of testing. Also, the applicant must provide the citation or a copy of the method used in the efficacy evaluation.
- The field data (two sites) submitted by the applicant are suitable for meeting the simulated use test requirement; however, concerns raised by this reviewer must be

addressed by the applicant. See below:

- Provide as much information as possible on the batch/lot of the chlorine dioxide produced, including the information on the reagents used to generate the chlorine dioxide: sodium hypochlorite, sodium chlorite, and hydrochloric acid.
- What surrogates were used at the USPS Curseen-Morris Processing and Distribution site for the BI strips?
- Provide a summary of what was known about the levels of *B. anthracis* spores in the treated environments prior to decontamination.
- Explain the occurrence of positive BI strips and how this impacts the assessment of product efficacy.
- The applicant must identify both porous and non-porous substrates sampled during remediation to support the label claims.

Feel free to contact me if you have any questions or concerns regarding this review. I can be reached at Tomasino.Stephen@epa.gov or by phone at 410-305-2976. Also, if requested, MLB will review additional information submitted by the applicant.

cc: Susan Lawrence, BEAD

Attachment 1

Product Performance Test Guidelines
OCSPP 810.2100: Sterilants—Efficacy Data Recommendations (2012)

(i) *Bacillus anthracis* (*B. anthracis*) claims. This section addresses efficacy tests for all products with claims to inactivate *B. anthracis* spores on inanimate surfaces. The Agency recommends three possible approaches, as described in paragraphs (h)(1)(i) through (h)(1)(iii) of this guideline.

(1) Water-soluble powders, liquid products, gases and vapors—(i) Test procedure for sterilant/sporicide plus *B. anthracis* claim. The Agency recommends use of the Official Methods of Analysis of AOAC International, Official Method 966.04 Sporicidal Activity of Disinfectants test (Ref. 1) to demonstrate the sterilant efficacy of products. For Bacillus subtilis, Method II should be followed when testing using porcelain penicylinders. Sixty carriers representing each of two types of surfaces (porcelain penicylinders and silk suture loops) should be tested against spores of both *B. subtilis* (ATCC 19659) and C. *sporogenes* (ATCC 3584) on three samples representing three different batches of the product, one of which should be ≥60 days old (240 carriers per sample, or a total of 720 carriers). The inoculum employed should provide a target count of 1×10^5 –1×10^6 spores per carrier. In addition, conduct a **confirmatory test** using virulent *B. anthracis* spores (or a surrogate acceptable to EPA) inoculated on thirty carriers representing each of two types of surfaces (porcelain penicylinders and silk suture loops) on two samples, representing two different batches of the product (a total of 120 carriers).

(A) Evaluation of sporicidal success. The product should kill all of the test spores on all of the initial and confirmatory carriers (840 carriers) without any failures (e.g. growth of test organism after carrier treatment).

(ii) Test procedure for sporicidal decontaminants--qualitative testing. The Agency recommends use of the Official Methods of Analysis of AOAC International, Official Method 966.04 Sporicidal Activity of Disinfectants test (Ref. 1) using virulent *B. anthracis* spores (or a surrogate acceptable to EPA). Sixty carriers representing either or both of two types of surfaces (porcelain penicylinders and/or silk suture loops) should be tested on three samples representing three different batches of product, one of which should be ≥60 days old. The inoculum employed should provide a target count of 1×10^5 –1×10^6 spores per carrier. If one surface type is tested, then there are 60 carriers per sample, or a total of 180 carriers; if both surfaces types are tested, then the total number of carriers is 360. Media sterility controls and system controls (check for aseptic technique during carrier transfer process) are recommended per the method.

(A) Evaluation of sporicidal success. The product should kill all of the test spores on all of the 180 (or 360) carriers without any failures (e.g., growth of test organism after carrier treatment).

(iii) Test procedure for sporicidal decontaminants--quantitative testing. The Agency recommends the use of a well developed, quantitative sporicidal test method acceptable to EPA using virulent *B. anthracis* spores (or a surrogate acceptable to EPA) on porous and/or nonporous surfaces acceptable to EPA. The inoculum employed should provide a target count of 1×10^7 spores per carrier. The product should be tested on three samples representing three different batches of product, one of which should be ≥60 days old. The number of carriers will vary depending on the test method. The coupon material(s) should be representative of those found at the site(s) that appear on the product's labeling, and be acceptable to EPA.

(A) Evaluation of sporicidal success. The product should achieve a mean log reduction of ≥6 logs based on recoverable spores.

(2) Simulated use testing for gas and vapor products—(i) Test procedure. In addition to conducting one of the three laboratory studies in paragraphs (k)(1)(i) through (h)(1)(iii) of this guideline, simulated-use testing should also be conducted for vapor and gas products. Protocols for the simulated-use test should be submitted to the Agency for review and approval prior to conducting the test. The testing should be conducted under conditions that are representative of the uses specified on the product's labeling, and in a setting that is representative of the label use site(s). For example, a product intended for use in a room or a large warehouse should be tested in an empty room or large chamber. The purpose of the test would be to assure that key parameters for efficacy (chemical concentration, temperature, relative humidity and contact time) are accurately monitored and maintained throughout the enclosed space, and establish product generation rate (lbs/hr) and rate/volume (lbs/hr/ft3).

(ii) Additional considerations. Important issues to consider in developing the protocol for this test include:

(A) The test should be conducted in a sealed enclosure at least the size of a typical office or other room that simulates the intended use pattern and designed to measure the distribution of the product and conditions needed to meet the measure of success in the laboratory efficacy test. Items that might be treated (e.g., dressers, upholstered furniture, carpet, etc.) during an actual fumigation, should be included in this test.

(B) The protocol should specify the dimensions of the enclosure, number and location of monitoring devices (e.g., for gas or vapor concentration, total mass of gas or vapor injected into the enclosure, temperature, relative humidity), product application equipment, heaters and fans, contact time, etc. The equipment used to monitor and maintain these test parameters should be described.

(C) All recorded test results pertaining to the test conditions/parameters should be submitted to the Agency. The maximum volume of space that can be treated with a particular unit should be reported to the Agency. The minimum total mass of gas or vapor required to maintain the required concentration and contact time per cubic foot of space to be decontaminated should be reported.

(D) Appropriate controls should be employed to assess both the sterility of the test system and viability of the spore inoculum. Uninoculated carriers and/or uninoculated biological indicators should be placed in the test chamber to assess sterility of the test environment. Unexposed inoculated carriers and/or biological indicators should be used to determine the suitability of the growth medium designed for the recovery of viable spores.

(E) This test must be conducted either in accordance with Good Laboratory Practices (GLP) per 40 CFR Part 160 or in a federal laboratory with an appropriate Quality Assurance Project Plan (QAPP).

(iii) Evaluation of sporicidal success. Measurements should show that the same concentration, temperature, and relative humidity, can be maintained for the required contact time needed to achieve 100% kill (i.e., no growth of the test organism on any of the carriers) in the qualitative laboratory test, or a $\geq 6_{10}$ log reduction in the quantitative test is demonstrated in the simulated-use test. In addition, measurements of the fumigant mass injection/generation rate (e.g., pounds/hour), divided by the volume of the simulated use test bed, that was used to arrive at the required generation rate/volume (e.g., pounds per hour/cubic foot) for the fumigation, should be included with the data, and listed on the product label.

Sign-In Sheet for Sabre Meeting

May 9, 2012

Room S-8671

9:00-10:00 AM

Name	Affiliation	E-mail Address	Phone Number
Eliza Blair	EPA/AD	blair.eliza@epa.gov	
Sam Eltami	SABRE	seltami@sabre	[illegible] 9136 [illegible] 13132
John Mason	Sabre	jmason@sabre	[illegible] 518 514-1572
EARL GOAD	EPA/AD/CTT	goad.earl@epa.gov	703 308 6230
Mark Hartman	EPA / AD / RM 82	hartman.mark@epa.gov	703-308-0734
Jeff Kempter	EPA/AD/IO	kempter.carlton@epa.gov	703-305-5448
Emily Mitchell	EPA/AD/PSB	mitchell.emily@epa.gov	703-308-8583
Tajah Blackburn	EPA/AD/PSB/EET	blackburn.tajah@epa.gov	703-308-0342

Pyne, Jaclyn

From: Blair, Eliza
Sent: Tuesday, January 29, 2013 3:22 PM
To: Sam Eltomi
Cc: Harris, Monisha; Pyne, Jaclyn
Subject: RE: EPA Registration 73139-G (recoding)

Hi Sam,

As per our conversation on the phone about your difficulty in locating any product chemistry and acute tox data used to register 73139-1, I looked into our rules regarding 100% repacks. Even though you are essentially repacking your old product for this new use, and the old product was a repack of two other companies' products, because this is now a new use (anthrax) it no longer qualifies as a repack and we need product chemistry and acute tox data. You should be able to generate this data from any GLP-compliant lab - this is a standard panel of tests that every new product has to go through.

Here's the example data matrix again, listing all the product chemistry/acute tox guideline numbers and names:
http://www.epa.gov/pesticides/bluebook/appendix-d/8570-35-selective-generic.pdf

Here's the guidance documents for how to perform the product chemistry:
http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series830.htm

Here are the documents for acute tox:
http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series870.htm

As I mentioned on the phone, I am leaving my position in a few days and Jaclyn Pyne will be taking over for me. She has been briefed on this case and should be cc'd on all future emails.

Thanks,
Eliza Blair
Product Reviewer
Antimicrobials Division
Environmental Protection Agency
(703) 308-7279
blair.eliza@epa.gov

From: Sam Eltomi <SEltomi@SabreCompanies.com>
To: Monisha Harris/DC/USEPA/US@EPA
Cc: Carlton Kempter/DC/USEPA/US@EPA, Eliza Blair/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA
Date: 01/14/2013 09:54 AM
Subject: RE: EPA Registration 73139-G (recoding)

Monisha
I checked with accounting and confirmed that revised payment has been made. I also learned that small business qualification was granted.

Thank you.
Sam

From: Harris.Monisha@epamail.epa.gov [mailto:Harris.Monisha@epamail.epa.gov]
Sent: Friday, December 28, 2012 11:27 AM
To: Sam Eltomi
Cc: Kempter.Carlton@epamail.epa.gov; Blair.Eliza@epamail.epa.gov; Mendelsohn.Mike@epamail.epa.gov
Subject: Fw: EPA Registration 73139-G (recoding)

Sam, I wanted to follow-up with you to ensure that you received the notice below. Please contact me if you have any questions or comments.

Monisha Harris
US Environmental Protection Agency
Product Manager 32, Antimicrobials Division
Office of Pesticide Programs
1200 Pennsylvania Ave. N.W. MC 7510P
Washington, DC 20460

Physical Address
One Potomac Yard
2777 Crystal Drive
Adington, VA 22202
Phone: 703-308-0410

----- Forwarded by Monisha Harris/DC/USEPA/US on 12/28/2012 12:25 PM -----

From: Monisha Harris/DC/USEPA/US

To: Sam Eltomi <SEltomi@SabreCompanies.com>

Cc: Carlton Kempter/DC/USEPA/US@EPA, Eliza Blair/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA

Date: 12/19/2012 04:33 PM

Subject: EPA Registration 73139-G (recoding)

Sam, I called and left you a voicemail message to inform you of the following, as mentioned in my message I wanted to recap and provide more information. We are recoding your submission to an A500 (new use, additional use; non-food, indoor, FIFRA §2(mm) uses) (http://www.epa.gov/pesticides/fees/tool/decisiontree/antimicrobial/action-codes/A500.html). The PRIA fee is $11,577 and it appears that you have applied for a 75% small business fee waiver, so your fee would be $2,895. The decision time is 9 months and your new due date would be mid September 2013, but the specific date can not be determined until we have finalized processing. My apologies again for the inconvenience.

Monisha Harris
US Environmental Protection Agency
Product Manager 32, Antimicrobials Division
Office of Pesticide Programs
1200 Pennsylvania Ave. N.W. MC 7510P
Washington, DC 20460

Physical Address
One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202
Phone: 703-308-0410

Pyne, Jaclyn

From: Sam Eltomi [SEltomi@SabreCompanies.com]
Sent: Tuesday, February 12, 2013 9:28 AM
To: Harris, Monisha
Cc: Pyne, Jaclyn
Subject: RE: Additional Documents EPA Reg. 73139-G

Monisha

Thank you for the update as to status of submission. In reference to your specific request for additional documents.

Anthrax Fumigation Plan: In the past, I do not recall use of this term for a plan. The terminology that has been used is Remedial Action Plan (RAP) and Sampling Action Plan(SAP) . In some cases, both were separate documents, and at times, I believe they were combined into one document. In summary, the RAP describes the process and actions to be taken to remediate. The SAP defined sampling requirements and was the basis for data review and building clearance for re entry. The RAP and SAP have been site specific and subject to lead agency approvals prior to fumigation. We believe the RAP and SAP contain specificity around the building and it's requirements but combined with fumigation manual, and label to provide for safe fumigation. Therefore, we do not have an Anthrax RAP/ and SAP plan till we have a building. The fumigation manual guides the safe pesticide application and I would suspect be referenced or combined in site specific RAP and or SAP.

Mold label Claims: Sabre does not have section 3 end use claims. Previous fumigation done by Sabre for mold have been done by temporary approvals with a 24C. I believe Sabre has three labels in three separate States that have been previously approved. In the past, a similar RAP and SAP was used for fumigation and was building specific. I also understand that the label and manual was one document as approved with each respective 24C. Do you want us to provide 24C label previously used. As a note, the current pending 73139-G is not claiming mold end use.

Thanks
Sam

From: Harris.Monisha@epamail.epa.gov [mailto:Harris.Monisha@epamail.epa.gov]
Sent: Monday, February 11, 2013 2:27 PM
To: Sam Eltomi
Cc: Pyne.Jaclyn@epamail.epa.gov
Subject: Additional Documents EPA Reg. 73139-G

Hi Sam,

We will be sending your submission over to our risk assessment branch so they can take a look at things. With that said, they are requesting to look at the following documents:

- Anthrax fumigation plan
- Anthrax fumigation manual (we have a copy)
- Anthrax proposed label (we have a copy)
- Mold label used for your other registered product
- Mold fumigation plan
- Mold fumigation manual
-

The above documents would be helpful for the risk assessor as they provide a preliminary review of your proposed application. Thanks for your attention.

Monisha Harris
US Environmental Protection Agency
Product Manager 32, Antimicrobials Division
Office of Pesticide Programs
1200 Pennsylvania Ave. N.W. MC 7510P
Washington, DC 20460

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DATA MATRIX

Date March 6, 2013	EPA Reg No./File Symbol 73139-2	Page 1 of 4
Applicant's/Registrant's Name & Address Sabre Oxidation LLC 1891 New Scotland Road Slingerlands, NY 12159	Product DIKLOR G	

Ingredient Sodium Chlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title	Date

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DATA MATRIX

Date March 6, 2013	EPA Reg No./File Symbol 73139-2	Page 1 of 4
Applicant's/Registrant's Name & Address Sabre Oxidation LLC 1891 New Scotland Road Slingerlands, NY 12159	Product DIKLOR G	

Ingredient Sodium Chlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1000	Background for Product Properties test guidelines				cite all
830.1550	Product identity and composition				cite all
830.1600	Description of materials used to produce the product				cite all
830.1620	Descripition of production process				cite all
830.1650	Descripition of formulation of process				cite all
830.1670	Discuss of formation of propoerties				cite all
830.1700	Preliminary Analysis				cite all
830.1750	Certfied limits				cite all
830.1800	Enforcement of limts				cite all
830.1900	Submittal of samples				cite all

Signature	Name and Title	Date

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DATA MATRIX

Date March 6, 2013	EPA Reg No./File Symbol 73139-2	Page 2 of 4
Applicant's/Registrant's Name & Address Sabre Oxidation LLC 1891 New Scotland Road Slingerlands, NY 12159	Product DIKLOR G	

Ingredient Sodium Chlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title	Date
	Sam Eltomi	3/6/2013

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 6, 2013	EPA Reg No./File Symbol 73139-2	Page 2/2of 4
Applicant's/Registrant's Name & Address Sabre Oxidation LLC 1891 New Scotland Road Slingerlands, NY 12159	Product DIKLOR G	

Ingredient Sodium Chlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	color				cite all
830.6303	physical state				cite all
830.6304	odor				cite all
830.6313	Elevated metal stability				cite all
830.6314	Oxidation/Reduction chemical incompatibility				cite all
830.6315	Flammabiltiy				cite all
830.6317	Storage stability				cite all
830.6319	Miscibility				cite all
830.6320	Corrosion characteristics				cite all
830.6321	Dielectric breakdown voltage				cite all
830.7000	pH				cite all
830.7050	UV/Viscible adsorbtion				cite all
830.7100	Viscosity				cite all
830.7200	Melting point/melting range				cite all
830.7300	Density/Relative density/bulk density				cite all

Signature	Name and Title	Date
	Sam Eltomi	3/6/2013

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 6, 2013	EPA Reg No./File Symbol 73139-2	Page 3 of 4
Applicant's/Registrant's Name & Address Sabre Oxidation LLC 1891 New Scotland Road Slingerlands, NY 12159	Product DIKLOR G	

Ingredient Sodium Chlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title sam Eltomi	Date 3/6/2013

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DATA MATRIX

Date March 6, 2013	EPA Reg No./File Symbol 73139-2	Page 3 of 4
Applicant's/Registrant's Name & Address Sabre Oxidation LLC 1891 New Scotland Road Slingerlands, NY 12159	Product DIKLOR G	

Ingredient Sodium Chlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7370	Dissociation constants in water				Cite all
830.7550-830.7570	Petition coefficient (n.octanol/water)				Cite all
830.7550-830.7860	water solubility				Cite all
830.7950	vapor pressure				cite all
830.6316	Explodibility				cite all
830.7220	Boiling point and boiling range				cite all

Signature	Name and Title	Date
	sam Eltomi	3/6/2013

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 6, 2013	EPA Reg No./File Symbol 73139-2	Page 4 of 4
Applicant's/Registrant's Name & Address Sabre Oxidation LLC 1891 New Scotland Road Slingerlands, NY 12159	Product DIKLOR G	

Ingredient Sodium Chlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title	Date
	sam Eltomi	3/6/2013

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 6, 2013	EPA Reg No./File Symbol 73139-2	Page 4 of 4
Applicant's/Registrant's Name & Address Sabre Oxidation LLC 1891 New Scotland Road Slingerlands, NY 12159	Product DIKLOR G	

Ingredient Sodium Chlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute oral toxicity Rat				Cite all
870.1200	Acute dermal toxicity Rat				Cite all
870.1300	Acute inhalation toxicity rat				Cite all
870.2400	Primary eye irritation rabbit				cite all
870.2500	primary dermal irritation				cite all
870.2600	Dermal sensitization				cite all

Signature	Name and Title sam Eltomi	Date 3/6/2013

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sabre Oxidation Technologies 1891 New Scotland Road Slingerlands, NY 12159– 518-514-1572	EPA Registration Number/File Symbol 73139-2
Active Ingredient(s) and/or representative test compound(s) Sodium Chlorite	Date February 21, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) As described on product label	Product Name DIKLOR G

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	3/6/2013	Sam Eltomi

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

21-Day Screen Completed by Contractor

21-Day Expires on 12/18/12

Jacket # 73139-G
MRID# _____

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Monisha Harris

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 03, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SABRE OXIDATION TECHNOLOGIES, INC.
2642 MARCO AVENUE
ODESSA, TX 79762

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 27-NOV-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 11-03, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

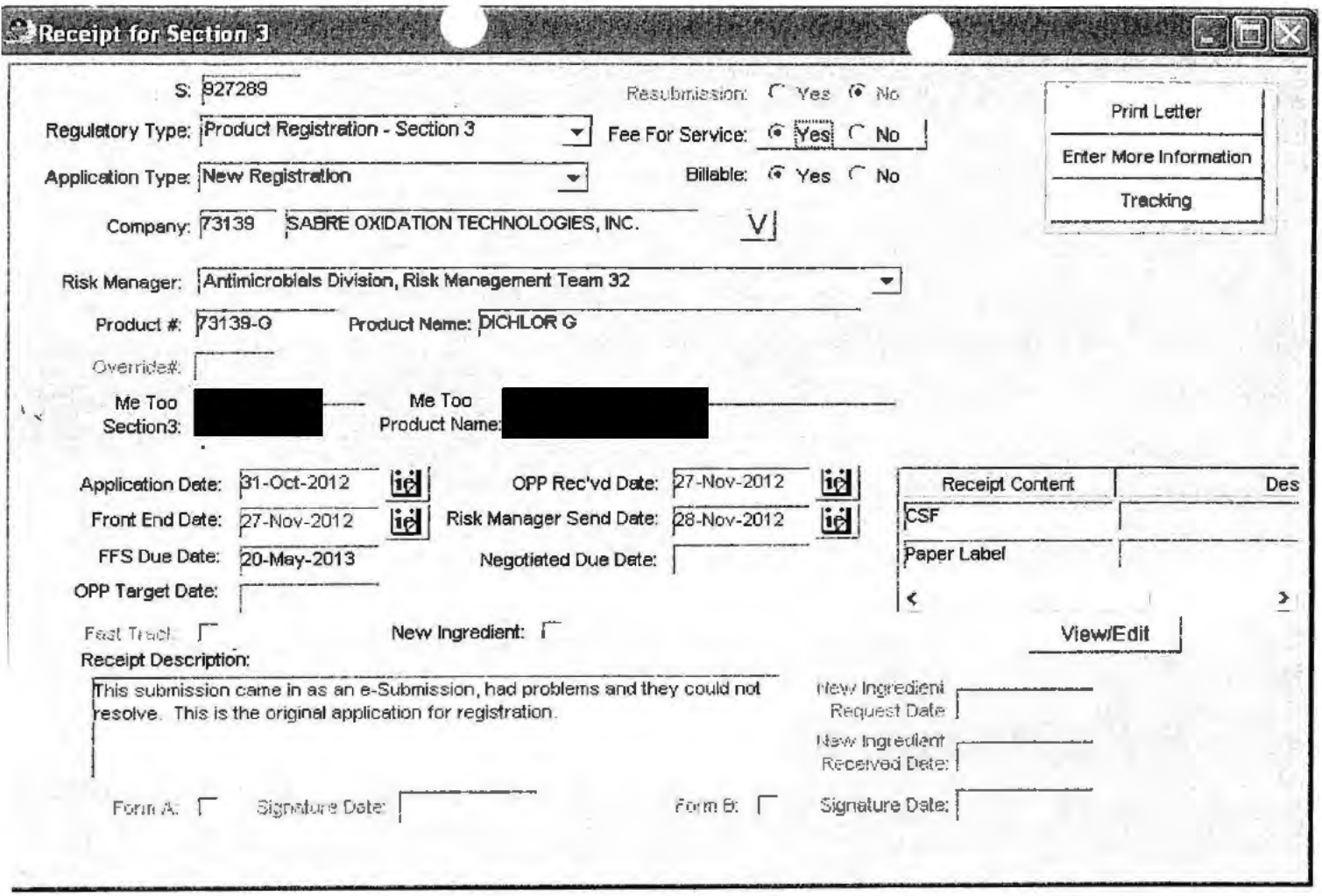
The rejected studies and their deficiencies are described below.

Studies___01____ - ___03_____ were all rejected for the following reasons/s:

* You failed to sign the statement of data confidentiality claims included in the study.

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submittedstudies) submitted to EPA. This statement must appearas page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

*No transmittal was included with the submission package.



Product ingredient source information may be entitled to confidential treatment

490023

Teresa Downs to: Sree Nair, Fiker Getachew 11/28/2012 01:37 PM

From: Teresa Downs/DC/USEPA/US
To: Sree Nair/DC/USEPA/US@EPA, Fiker Getachew/DC/USEPA/US@EPA
History: This message has been replied to.

This submission was received in late October on a CD accompanied by a paper copy of the submission . Geri was never able to get them to provide an acceptable e-Submission, so yesterday the documents were uploaded manually to Documentum. Please process the three documents in this submission electronically, although all will fail the 2011-3 review. I have changed the submission date to 11/27 since they never did provide an acceptable submission.

Teresa Downs
Information Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
phone: (703)305-5363
fax: (703)305-7670
www.epa.gov/pesticides

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 03, 2012

SABRE OXIDATION TECHNOLOGIES, INC.
2642 MARCO AVENUE
ODESSA, TX 79762

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 27-NOV-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 11-03, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

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*No transmittal was included with the submission package.

Sign-In Sheet for Sabre Meeting

September 25, 2012

Room S-8621

1:00-2:00 PM

Name	Affiliation	E-mail Address	Phone Number
Eliza Blair	EPA/AD	blair.eliza@epa.gov	703-308-7279
Jeff Kempter	EPA/AD	Kempter.carlton@epa.gov	703-305-5748
EARL GOAD	EPA/AD	goad.earl@epa.gov	703 308 6225
IAN BLACKWELL	EPA/AA/PSB/CTI	Blackwell.Ian@EPA.	703-605-0565
Sam Eltomi	SABRE	seltomi@solveco.mpanies.com	913-669-3132

RE: Additional Documents EPA Reg. 73139-G
Sam Eltomi
to:
Monisha Harris
02/12/2013 09:28 AM
Cc:
Jaclyn Pyne
Hide Details
From: Sam Eltomi <SEltomi@SabreCompanies.com>

To: Monisha Harris/DC/USEPA/US@EPA

Cc: Jaclyn Pyne/DC/USEPA/US@EPA

- formulation exemptions
- product specific ↑ date
- tox
- certification
- cited chlorine generator

data gaps
- methods
- matrix data
to cite-all

1 Attachment

image001.gif

Monisha

Thank you for the update as to status of submission. In reference to your specific request for additional documents.

– not required

Anthrax Fumigation Plan: In the past, I do not recall use of this term for a plan. The terminology that has been used is Remedial Action Plan (RAP) and Sampling Action Plan(SAP) . In some cases, both were separate documents, and at times, I believe they were combined into one document. In summary, the RAP describes the process and actions to be taken to remediate. The SAP defined sampling requirements and was the basis for data review and building clearance for re entry. The RAP and SAP have been site specific and subject to lead agency approvals prior to fumigation. We believe the RAP and SAP contain specificity around the building and it's requirements but combined with fumigation manual, and label to provide for safe fumigation. Therefore, we do not have an Anthrax RAP/ and SAP plan till we have a building. The fumigation manual guides the safe pesticide application and I would suspect be referenced or combined in site specific RAP and or SAP.

Mold label Claims: Sabre does not have section 3 end use claims. Previous fumigation done by Sabre for mold have been done by temporary approvals with a 24C. I believe Sabre has three labels in three separate States that have been previously approved. In the past, a similar RAP and SAP was used for fumigation and was building specific. I also understand that the label and manual was one document as approved with each respective 24C. Do you want us to provide 24C label previously used. As a note, the current pending 73139-G is

not claiming mold end use.

Thanks
Sam

From: Harris.Monisha@epamail.epa.gov [mailto:Harris.Monisha@epamail.epa.gov]
Sent: Monday, February 11, 2013 2:27 PM
To: Sam Eltomi
Cc: Pyne.Jaclyn@epamail.epa.gov
Subject: Additional Documents EPA Reg. 73139-G

Hi Sam,

We will be sending your submission over to our risk assessment branch so they can take a look at things. With that said, they are requesting to look at the following documents:

- Anthrax fumigation plan
- Anthrax fumigation manual (we have a copy)
- Anthrax proposed label (we have a copy)
- Mold label used for your other registered product
- Mold fumigation plan
- Mold fumigation manual
-

The above documents would be helpful for the risk assessor as they provide a preliminary review of your proposed application. Thanks for your attention.

Monisha Harris
US Environmental Protection Agency
Product Manager 32, Antimicrobials Division
Office of Pesticide Programs
1200 Pennsylvania Ave. N.W. MC 7510P
Washington, DC 20460

Physical Address
One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202
Phone: 703-308-0410

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 02, 2013

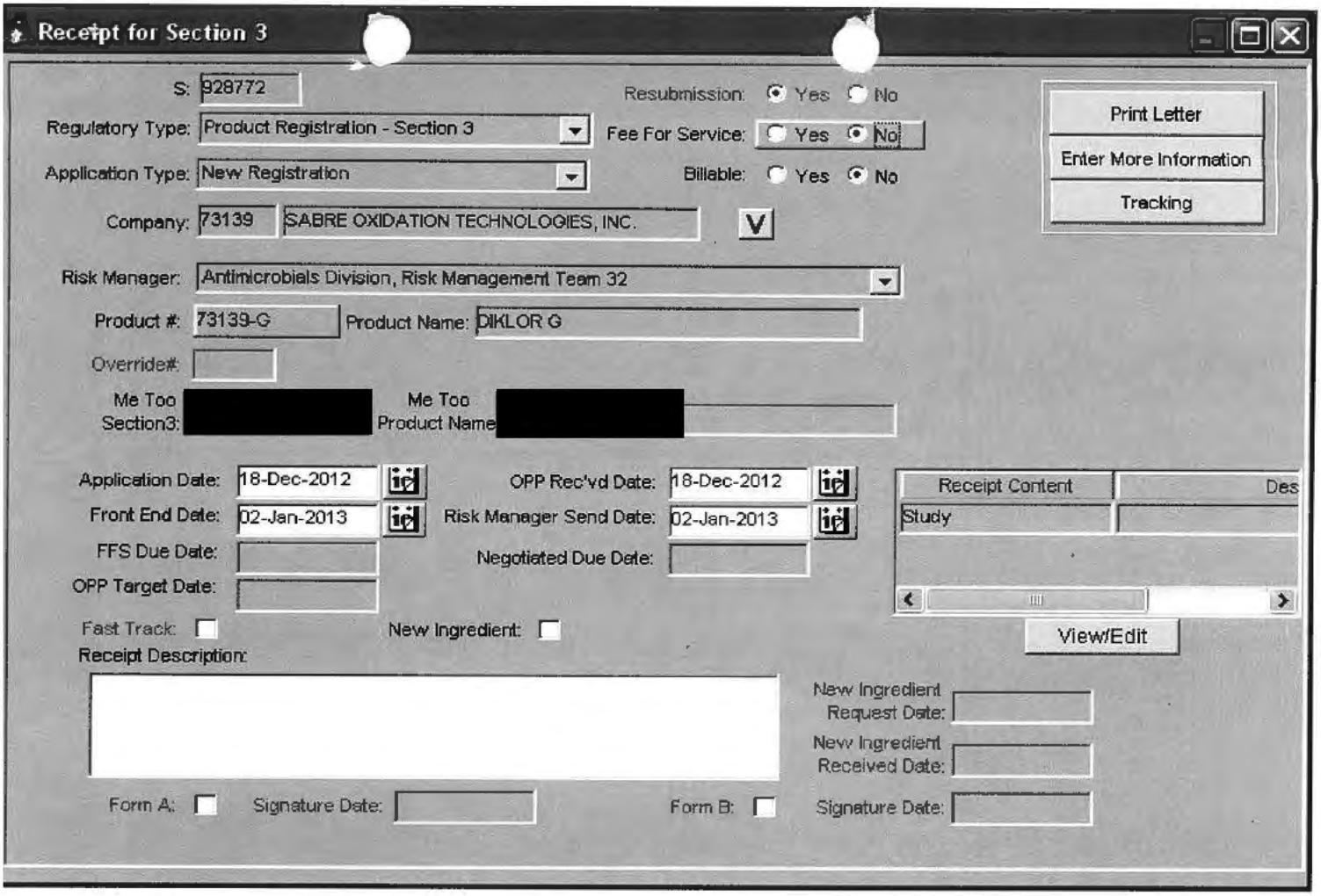
OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SABRE OXIDATION TECHNOLOGIES, INC.
2642 MARCO AVENUE
ODESSA, TX 79762

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 18-DEC-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Product ingredient source information may be entitled to confidential treatment

Transmittal Document

Submitter:

Sabre Oxidation Technologies

EPA company number: 73139

Submission Date:

12/18/12

Actions Supported:

EPA file symbol: 73139-G

Documents:

49029601 Evaluation of chlorine dioxide gas generator

49029602 Chlorine dioxide gas fumigation of the in-activation of Bacillus anthraces spores in contaminated buildings or structures, report dated May, 2003

49029603 Chlorine dioxide gas fumigation of the in-activation of Bacillus anthraces spores in contaminated buildings or structures, report dated January, 2004

49029604 Evaluation of sporicidal decontamination technologies

Decision #: 472355
DP #: (407918)
PRIA
Parent DP #:
Submission #: 927289
E-Sub #:

DATA PACKAGE BEAN SHEET

Date: 03-Jan-2013

* * * Registration Information * * *

Registration: 73139-G - DIKLOR G

Company: 73139 - SABRE OXIDATION TECHNOLOGIES, INC.

Risk Manager: RM 32 - Monisha Harris - (703) 308-0410 Room# PY1 S-8834

Risk Manager Reviewer: Eliza Blair EBLAIR

Sent Date: TENTATIVE Due Date: 18-Sep-2013 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A500) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 020502, Sodium chlorite(25%)

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 28-Dec-2012 Due Back:

DP Ingredient: 020502, Sodium chlorite

DP Title: Efficacy

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	AD / PSB			Last Possible Science Due Date: 29-Jun-2013
Team Name:	EET			Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Please review the efficacy data sumitted in support of a new product.

Technical Screen Due Date is February 4, 2013. PRIA due date is September 18, 2013. Thx!

DP#: (407918) *** Studies Sent for Review * Decision#: (472355)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49029601		Stone, H.; Rogers, J.; Choi, Y.; et al. (2006) Evaluation of Chlorine Dioxide Gas Generator. Unpublished study prepared by U.S. Environmental Protection Agency. 30p.		
49029602		Mason, J.; Eltomi, S.; Skodack, D. (2003) Chlorine Dioxide Gas Fumigation of t he In-Activation of Bacillus anthraces Spores in Contaminated Buildings or Structures. Unpublished study prepared by BioTest Laboratories, Microbiology Specialists, Inc. and Armed Forces Radiobiology Research Institute. 26p.		
49029603		Mason, J.; Eltomi, S.; Skodack, D. (2004) Chlorine Dioxide Gas Fumigation of the In-Activation of Bacillus anthraces Spores in Contaminated Buildings or Structures. Unpublished study prepared by Sabre Oxidation Technologies, Inc. 54p.		
49029604		Kelly, T.; Willenberg, Z.; Skodack, D. (2005) Evaluation of Sporicidal Decontamination Technologies. Unpublished study prepared by Battelle and Sabre Oxidation Technologies, Inc. 40p.		

32

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 11/27/12

Experts In-Processing Signature: MP Date 12/3/12 Fee Paid: Yes ✓

Division management contacted on issues No ____ Yes ____ Date ____

EPA Reg. Number: 73139-G	EPA Receipt Date: 11/27/12

	Items for Review	Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type	X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)	X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) 100% Repack — yes / no			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X
	Certificate and data matrix consistent			
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) — yes / no			
	If applicable, is there a letter of Authorization for exclusive use only.			
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X
	a) Selective Method (Fee category experts use) — yes / no			
	b) Cite-All (Fee category experts use)			
	c) Applicant owns all data (Fee category experts use)			
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels **)**	X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)			X
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

X AI + % Comp add. L.

X 100% repack Submission MB

X Data package N/A

X Jacket approved.

MRID: N/A

IK S-4613

703-347-8518

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

A540 - New end use product.

100 % Peracle

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition			
830.1600	Description of materials used to produce the product			
830.1650	Description of formulation process			
830.1670	Discussion on the formation of impurities			
830.1700	Preliminary analysis			
830.1750	Certified limits (158.345)			
830.1800	Enforcement analytical method			

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color			
830.6303	Physical State			
830.6304	Odor			
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)			
830.6315	Flammability			
830.6316	Explodability			
830.6317	Storage stability*			
830.6319	Miscibility			
830.6320	Corrosion Characteristics*			
830.6321	Dielectric Breakdown Voltage			
830.7000	pH			
830.7050	UV/ Visible Absorption			
830.7100	Viscosity			
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density			
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required *May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:
1) supply the product specific acute toxicity 6 pack data (listed below),
2) provide a bridging rationale document or waiver request or,
3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)				
830.1200	Acute Dermal (LD50)				
830.1300	Acute Inhalation (LC50)				
830.2400	Acute Eye Irritation				
830.2500	Acute Dermal Irritation				
830.2600	Dermal Sensitization				

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 30, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-472355
EPA File Symbol or Registration Number: 73139-G
Product Name: DICHLOR G
EPA Receipt Date: 27-Nov-2012
EPA Company Number: 73139
Company Name: SABRE OXIDATION TECHNOLOGIES, INC.

SAM ELTOMI
SABRE OXIDATION TECHNOLOGIES, INC.
1891 NEW SCOTLAND ROAD
SLINGERLANDS, NY 12159

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Please remit payment in the amount of $3,473 (fee for action code A540 is $4,631 minus payment of $1,158) within 14 days to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (314) 418-4990

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 14 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{927289\~

This package includes the following

- ◉ New Registration
- ○ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 32

Receipt No. S- [redacted] 927289

EPA File Symbol/Reg. No. 73139-G

Pin-Punch Date: 11/[redacted]/2012

27

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A540

Granted: A540

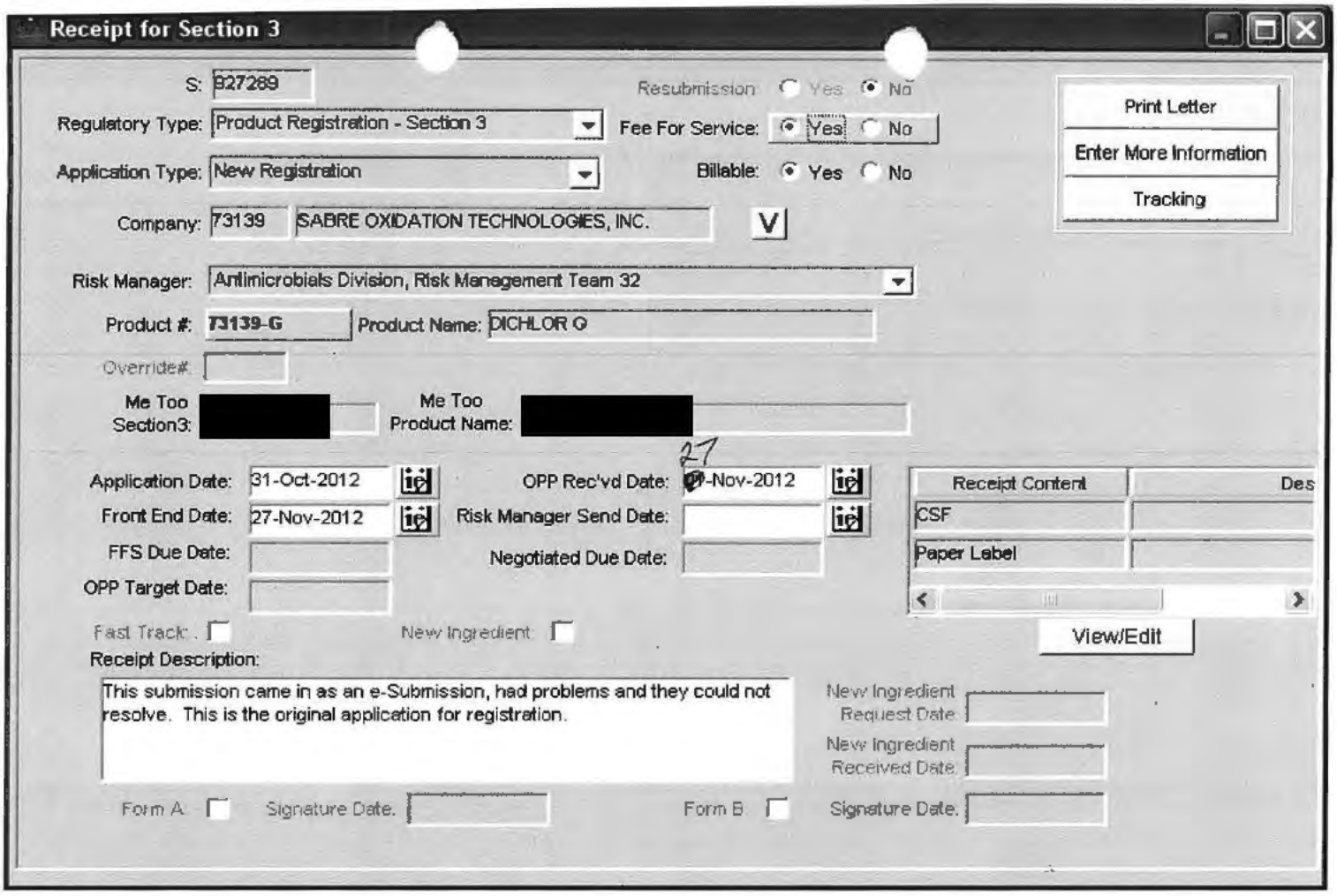
Amount Due: $ 4631.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: TRAN41 (JC) Date: 11/27/12

Remarks:



Product ingredient source information may be entitled to confidential treatment

contact for this product

Mike Myers [redacted]

Personal privacy information

Online Payment

Online Payment

Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 258COP2T
Agency Tracking ID: 74370016350
Transaction Date and Time: 10/22/2012 14:50 EDT

Payment Summary

Address Information

Account Holder Name: John Mason
Billing Address: 1891 New Scotland Road
Billing Address 2:
City: SLINGERLANDS
State / Province: NY
Zip / Postal Code: 12159
Country: USA

Account Information

Card Type: American Express
Card Number: **********9003
Decision Number:
Registration Number: [redacted]
Company Name: Sabre Oxidation Technolog
Company Number: 73139-2
Action Code: A540

Payment Information

Payment Amount: $1,158.00
Transaction Date and Time: 10/22/2012 14:50 EDT

Product ingredient source information may be entitled to confidential treatment

Please read instructions on reverse before completing form. Form Approved OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
73139-2	Monisha Harris	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
DIKLOR G	32	

5. Name and Address of Applicant *(Include ZIP Code)*

Sabre Oxidation Technologies
1891 New Scotland Road
Slingerlands, NY 12159

[X] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. [redacted]

Product Name [redacted]

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[X] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [X] Container	Drum, IBC, Bulk	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [X] Lithograph [ ] Paper glued [ ] Stenciled [X] Other Bulk Label

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Sam Eltomi	V P of Technology	913-669-3132

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
[signature]	Chief Technology Officer
4. Typed Name	**5. Date**
John Mason	8/1/2012

EPA Form 8570-1 (Rev. 6-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Product ingredient source information may be entitled to confidential treatment

Sabre Oxidation Technologies
1891 New Scotland Road
Slingerlands, NY 12159
518.514.1572
www.sabretechservices.com

December 12, 2012

U. S. Environmental Protection Agency
Document Processing Desk (Resubmission)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Subject : DIKLOR G Product Registration 73139-2

Dear Ms. Monisha Harris

Thank you for your support on our most recent product registration submission. Per your request, Please find requested items as outlined in December 07, 2012 email.

Enclosed documents are

- Form 8570-27
- Form 8570-34
- Form 8570-35
- Four studies that support registration with cover sheet
- Fumigation user manual
- Product Label

Again, thank you, and my thanks to Eliza and Jeff for all their assistance. If you have any questions, please contact me at the above address or 913-669-3132.

Thank you

Sam Eltomi
Sabre Energy Systems LLC
V.P of Technology

Encl.

Sabre Oxidation Technologies, Inc.
1891 New Scotland Road
Slingerlands, NY 12159
Tel: (518) 514-1572
Fax: (518) 439-1567

October 31, 2012

FEDERAL EXPRESS OVERNIGHT MAIL

Document Processing Desk 7502P
(E-SUB)
U.S. EPA
Office of Pesticide Programs
2777 S. Crystal Drive
Arlington, VA 22202

Attn: Gerri McCann

Re: **Registration of DIKLOR ™G**
Company Product No: 73139-2

Dear Ms. McCann:

Pursuant to our telephone conversation today, enclosed herewith for your consideration is a new .pdf file of the label on a CD-Rom to replace the one submitted on October 24, 2012.

If you have any questions or need anything further, please contact me or my assistant, Pam Morrison

Sincerely,

By: John Y. Mason (AM)
John Y. Mason
Chief Technology Officer

3544 — xml and pdf did not match — Rejected

Sabre Oxidation Technologies, Inc.
1891 New Scotland Road
Slingerlands, NY 12159
Tel: (518) 514-1572
Fax: (518) 439-1567

October 24, 2012

FEDERAL EXPRESS OVERNIGHT MAIL

Document Processing Desk 7502P
(E-SUB)
U.S. EPA
Office of Pesticide Programs
2777 S. Crystal Drive
Arlington, VA 22202

Re: **Registration of DIKLOR ™G**
Company Product No: 73139-2

Dear Sir/Madam:

Enclosed herewith for your consideration is our application for pesticide registration of DIKLOR G and the following supporting papers:

1. EPA Form 8570-1;
2. EPA Form 8570-4
3. Five (5) copies of the DIKLOR G label;
4. .pdf file of the label on a CD-ROM;
5. Receipt of Payment; and
6. Certification with Respect to Label Integrity.

If you have any questions or need anything further, please contact me or my assistant, Pam Morrison

Sincerely,

fisher

By: _____
John Y. Mason
Chief Technology Officer

SOTI016-02/02/2009

orm approved. OMB No. 2070-0060, 2070-0057, 207 07, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Sabre Oxidation Technologies 1891 New Scotland Rd. Slingerland NY 12159	73139-2
	Product Name DIKLOR G
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 12/04/2012

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Sodium Chlorite

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Sodium Chlorite	[redacted]	[redacted]
or	or	or
Sodium Chlorite	[redacted]	[redacted]

Signature	Name and Title	Date
	Sam Eltomi, VP of Technology	12/10/2012

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 12/10/2012	EPA Reg No./File Symbol 73139-2	Page 1 of 1
Applicant's/Registrant's Name & Address Sabre Oxidation Technologies 1891 New Scotland Rd. Slingerland NY 12159	Product DIKLOR G	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Field Data	Chlorine Dioxide Gas Fumigation-Inactivation of Bacillus	See attached	Sabre Oxidation	complete	Curseen Morris
Field Data	Chlorine Dioxide Gas Fumigation-Inactivation of Bacillus	see attached	Sabre Oxidation	complete	Trenton
EPA Report	Evaluation of Sporicidal Decontamination Technologies	see attached	US-EPA	complete	Attached
EPA Report	Evalution of Chlorine Dioxide Gas Generator	see attached	US-EPA	complete	Attached

Signature	Name and Title	Date

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sabre Oxidation Technologies, 1891 New Scotland Rd., Slingerland NY12159	EPA Registration Number/File Symbol 73139-2
Active Ingredient(s) and/or representative test compound(s) Sodium chlorite	Date 12/8/2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Greenhouse nonfood,Indoor nonfood.Residential indoor and outdoor.Terrestrial nonfood	Product Name DIKLOR G

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

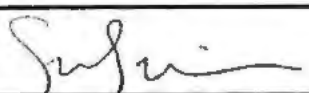
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	12/10/2012	Sam Eltomi

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL

EPA Registration #	Date Submitted to EPA	Electronic file name
73139-2	11-24-12	DIKLORO Chlorine Dioxide Sterilant Precursor

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

October 23, 2012
Date

John Y Mason

Name (typed) John Y. Mason

Chairman / CTO

Title

For use only by:

- Federal On-Scene Coordinators and contractors and other trained federal/state/local response personnel under the FOSC's supervision;
- Trained U.S. Military personnel and contractors under their supervision;
- Persons who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) following completion of the required training.

Under the terms and conditions of this product's registration, this product may only be sold or distributed by the registrant directly to the persons identified above.

DIKLOR ™G Chlorine Dioxide Sterilant Precursor

SPORICIDAL DECONTAMINANT for INACTIVATION of *Bacillus anthracis* SPORES on PRECLEANED, HARD, NON-POROUS and POROUS SURFACES

DIKLOR ™G Chlorine Dioxide Sterilant Precursor is a sporicidal decontaminant that inactivates *Bacillus anthracis* spores on precleaned, hard, nonporous and porous surfaces at certain sites when used in accordance with all precautions and directions specified on this label and in the attached Fumigation Manual.

ACTIVE INGREDIENT:
Sodium Chlorite ---------- 25.0%
OTHER INGREDIENTS:---------- 75.0%
TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE (SIDE) (BACK) PANEL FOR ADDITIONAL

PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg. No. 73139-
EPA Est. No.---------

Sabre Oxidation Technologies
2642 Marco Avenue
Odessa, TX 79762
Emergency Phone Number
1-800-222-1222

FIRST AID	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or physician for treatment advice.
IF SWALLOWED	Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor immediately for treatment advice.
NOTE TO PHYSICIAN: Probably mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Irritating to nose and throat. Do not breathe dust or vapors. Do not get in eyes, on skin or clothing. Do not handle with bare hands. Wear protective eyewear (goggles or face shield), clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Other chemical may be co-located for this process, refer to fumigation manual and respective Material Safety Data Sheet for chemical specific details.

PPE REQUIRED FOR PROTECTION FROM *BACILLUS ANTHRACIS* SPORES

When applying the product to areas contaminated with *Bacillus anthracis* spores, wear the personal protective equipment (PPE) described in this product's Fumigation Manual, the Fumigation Management Plan, or the Remediation Action Plan or equivalent plan.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS
Dry DIKLOR G is a strong oxidizing agent. Only mix into or dilute with water or non-oxidizable materials. Mixing with acids or other chemicals may start a chemical reaction with the generation of heat liberation of a hazardous gas (chlorine dioxide), and possible fire or explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty rags or any other foreign matter. Contact with acids may release toxic gas. Use only clean, dry utensils when handling.

EMERGENCY HANDLING
In case of contamination or decomposition, do not reseal container. If possible, isolate container in an open and well-ventilated area. Flood with large volumes of water. If fire occurs, extinguish fire by applying large volumes of water. Cool any unopened drums near the fire by spraying with water.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
STORAGE: Keep product dry in tightly closed container when not in use. Do not drop, roll or skid drum. Keep upright. Always replace cover. Store this product in a cool, dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water. Do not reuse empty container.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:
Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Offer for reconditioning, if appropriate. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For use as a sporicidal decontamination to inactivate *Bacillus anthracis* spores in sealed, pre-cleaned structure up to 17,000,000 cubic feet. Applications may be made in industrial, commercial, educational, agricultural, residential, governmental, military, parking and storage, religious, transit structures (offices, schools, airports, nursing homes, colleges, libraries, museums, theaters, factories, power utility plants and other light and heavy industrial plant, breweries, foundry, mines, chemical plants and refineries, warehouses, trains, subways, personal and commercial vehicles, banks, bars, hotels, hospitals and medical centers, malls, fixed or mobile storage vessels, bus station, boat house, cruise ship, military ship, container and non-container ship, recreational and non-recreational ships, recreational and non-recreational facilities, residential structures, stadiums, marinas, submarines and other submerged structures, nurseries, public retail outlets and eatery, apartments, taxi, condominiums, restaurants, garages, ferries and ferry slips, taxi and taxi station, empty silo, courthouses, embassies, city halls, fire, station, police stations, post offices, prisons, caves, tunnels, farms, barns, empty animal house, cellars dairies, worship buildings, water treatment facilities, storage tanks, wells and well houses, sewers and lift stations, rail cars and stations, train stations, commercial, private, shipping and military airplanes and

hangars, barracks, bunkers, monuments, and emergency response vehicles). Use only with Sabre application equipment.

This product is for use in Sabre application equipment only, and by trained personnel trained by Sabre. Read manual for directions of DIKLOR G Sterilant applications. See SABRE Fumigation Manual for operating procedures of the Sabre application equipment. Do not use this product without development of an appropriate Fumigation Management Plan, Remediation Action Plan or equivalent. For application on structures and contents contaminated with *Bacillus anthracis* spores, the application shall be performed by Sabre under the supervision of the EPA, or by EPA with personnel that have been trained and certified by Sabre.

CHLORINE DIOXIDE GENERATION

DIKLOR G™ is a precursor for the sterilant agent, chlorine dioxide. DO NOT ADD DIKLOR ™ G directly to system being treated. Aqueous solutions of chlorine dioxide can be generated from DIKLOR G by any of the following methods:

1. The chlorine gas method, which utilizes DIKLOR™ G and chlorine gas,
2. The hypochlorite (bleach) method, which utilizes DIKLOR™TG, a hypochlorite solution and an acid,
3. The Acid-Chlorite method, which utilizes DIKLOR™ G and an acid,
4. The electrolytic method, which utilizes DIKLOR™ G via electrochemical process

The above generation methods produces a chlorine dioxide solution (0-4,000 ppm) from the effluent of the Sabre generator. Sabre Representative can guide you in the selection, installation and operation of generation systems and the proper injection of chlorine dioxide. Consult and follow all instructions in chlorine dioxide generation system in manual when using this product. Also, read and follow the Fumigation Manual and any applicable Remediation Action Plan (or equivalent) for this product.

IMPORTANT NOTICE: Seller warrants product conforms to its chemical description and is reasonably fit for the purposes stated on the label under normal conditions of use. THE FOREGOING WARRANTIES ARE EXCLUSIVE AND ARE IN LIEU OF ALL OTHER WARRANTIES, WHETHER WRITTEN, ORAL OR IMPLIED. THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, IN OTHER RESPECTS THAN AS EXPRESSLY SET FORTH HEREIN, ARE EXPRESSLY EXCLUDED AND DISCLAIMED.

NOTE: Buyer assumes all responsibility for safety and use not in accordance with directions

Pages 98-100 *Confidential Statement of Formula may be entitled to confidential treatment*